

## **Exhibit B**

UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

FORM 10-K

(Mark One)

☒ ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the fiscal year ended December 31, 2010

OR

☐ TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934  
For the transition period from \_\_\_\_\_ to \_\_\_\_\_

Commission file number 0-50295

**ADVANCED CELL TECHNOLOGY, INC.**  
(Exact name of registrant as specified in its charter)

**Delaware**  
(STATE OR OTHER JURISDICTION OF  
INCORPORATION OR ORGANIZATION)

**87-0656515**  
(I.R.S. EMPLOYER IDENTIFICATION NO.)

**33 Locke Drive, Marlborough, Massachusetts 01752**

**(508) 756-1212**

(Address and telephone number, including area code, of registrant's principal executive offices)

Securities registered pursuant to Section 12(b) of the Act:  
None.  
(Title of Class)

Securities registered pursuant to Section 12(g) of the Act:  
Common Stock, \$0.001 par value per share  
(Title of Class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. Yes ☒ No ☐

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§ 229.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes ☐ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one):

Large accelerated filer ☐

Accelerated filer ☒

Non-accelerated filer ☐

Smaller reporting company ☐

(Do not check if a smaller reporting company)

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act.) Yes ☐ No ☒

The aggregate market value of the registrant's Common Stock held by non-affiliates of the registrant (based upon the closing price of \$0.08 for the registrant's Common Stock as of June 30, 2010) was approximately \$65.5 million (based on 818,397,859 shares of common stock outstanding and held by non-affiliates on such date). Shares of the registrant's Common Stock held by each executive officer and director and by each entity or person that, to the registrant's knowledge, owned 5% or more of the registrant's outstanding Common Stock as of June 30, 2010 have been excluded in that such persons may be deemed to be affiliates of the registrant. This determination of affiliate status is not necessarily a conclusive determination for other purposes.

The number of outstanding shares of the registrant's Common Stock, \$0.001 par value, was 1,506,715,382 shares as of March 11, 2011.

ADVANCED CELL TECHNOLOGY, INC.  
2010 ANNUAL REPORT ON FORM 10-K  
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## CAUTIONARY STATEMENT RELATING TO FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K and the information incorporated by reference includes "forward-looking statements." All statements regarding our expected financial position and operating results, our business strategy, our financing plans and the outcome of any contingencies are forward-looking statements. Any such forward-looking statements are based on current expectations, estimates, and projections about our industry and our business. Words such as "anticipates," "expects," "intends," "plans," "believes," "seeks," "estimates," or variations of those words and similar expressions are intended to identify such forward-looking statements. Forward-looking statements are subject to risks and uncertainties that could cause actual results to differ materially from those stated in or implied by any forward-looking statements.

## PART I

### Item 1. Business

#### *Overview*

Advanced Cell Technology, Inc., a Delaware corporation (the "Company", "we", "us", or "our") is a biotechnology company focused on developing and commercializing human embryonic and adult stem cell technology in the emerging field of regenerative medicine.

We were incorporated in Nevada under the name Two Moon Kachinas Corp. on May 18, 2000. On December 30, 2004, we filed an amendment to our articles of incorporation to change our corporate name to A.C.T. Holdings, Inc. On January 31, 2005, we completed the acquisition of Advanced Cell Technology, Inc., a Delaware corporation (prior to the Reincorporation (as defined below), "ACT"), pursuant to the terms of an Agreement and Plan of Merger dated January 3, 2005. As a result of the transaction, we terminated our kachina doll business and succeeded to the business operations and research efforts of ACT in the field of biotechnology. On June 17, 2005, we filed an amendment to our articles of incorporation to change our corporate name to Advanced Cell Technology, Inc. On November 18, 2005, we consummated a merger with and into our wholly-owned subsidiary ACT (the "Reincorporation"). As a result of the Reincorporation, we became a Delaware corporation.

We have acquired, developed and maintain a portfolio of patents and patent applications that form the proprietary base for our research and development efforts in the area of embryonic and adult stem cell research. We believe that our intellectual property portfolio is one of the strongest in the field. Our team includes some of the world's leading scientists in the field of stem cell research and development, and experts in conducting clinical trials. We believe our technology base, combined with our know-how, provides us with a strong competitive advantage and will facilitate the successful development and commercialization of products for use in the treatment of a wide array of chronic, degenerative diseases and in regenerative repair of a variety of acute diseases, such as trauma, myocardial infarction and burns.

Our belief that our intellectual property represents one of the strongest portfolios in the field is supported by:

- The early and consistent pace of filing, and the breadth of the large number of filings in the portfolio.
- The relative immaturity of this field of study.
- The limited number of truly competitive portfolios of intellectual property.

Regenerative medicine is a new and emerging field of study involving development of medical therapies based on advances in stem cell and nuclear transfer technology. We have developed and maintain a broad intellectual property (IP) portfolio, with ownership or exclusive licensing of over 28 issued patents and over 170 patent applications in the field of regenerative medicine and related areas. This significant volume of patents and patent licenses has been developed in the short span of approximately the past eight to eleven years.

Although we have strong competitors in this field, they are limited in number. We believe our intellectual property portfolio compares favorably with those of our competition based upon its size, focus and filing dates. With respect to the focus of our human embryonic stem cell portfolio, we believe that somatic cell nuclear transfer and chromatin transfer are, and will prove to be, one of the technological keys to successful development of stem cell therapies (see "Cellular Reprogramming," below). In addition, we have succeeded in deriving human embryonic cell lines without destroying the donor embryo through our proprietary single blastomere derivation technology. We own or have a license to numerous other technologies for dealing with transplant rejection, including means of activating oocytes during nuclear transfer, parthenogenesis, transdifferentiation, and dedifferentiation. Our intellectual property also includes patent rights and applications for specific applications of stem cell technology in producing retinal pigment epithelium (RPE), hemangioblasts, myoblast stem cells and numerous methods and compositions for the use of these technologies and derived cells in retinal disease, heart disease, immunodeficiency states and cancer.

The company has secured Food and Drug Administration (FDA) clearance to proceed to a Phase II Clinical Trial for its Myoblast program for the treatment of heart failure, and the trial is currently being developed. We believe that the company's myoblast technology has demonstrated that a myoblast transplantation treatment is feasible and safe in clinical trials conducted to date and that the technology could address the large market potential presented by heart failure.

Our research efforts to date in human embryonic technologies are at the level of clinical trials, pre-clinical development and basic research. In November of 2009 we filed an Investigational New Drug (IND) Application with the US Food and Drug Administration (FDA) to initiate a Phase I/II multicenter study using embryonic stem cell derived retinal cells to treat patients with Stargardt's Macular Dystrophy (SMD), as part of our RPE program. These retinal cells were developed using our proprietary blastomere derivation techniques.

The company's Hemangioblast program for the treatment of Diseases and Disorders of Circulatory and Vascular System is in preclinical development. These precursor cells derived from human embryonic stem (ES) cells can be used to achieve vascular repair in animal models of vascular injury.

We are focused on leveraging our key assets, including our intellectual property, our scientific team, our facilities and our capital, to accelerate the advancement of our stem cell technologies. In addition, we continue to pursue strategic collaborations with members of academia, industry and foundations to further accelerate the pace of our research efforts.

#### *The Field of Regenerative Medicine*

The emerging field of treatment called "regenerative medicine" or "cell therapy" refers to treatments that are founded on the concept of producing new cells to replace malfunctioning or damaged cells as a vehicle to treat disease and injury. Our focus is the development of effective methods to generate replacement cells from both human embryonic and adult stem cells.

Many significant and currently untreatable human diseases arise from the loss or malfunction of specific cell types in the body. This is especially true of diseases associated with aging such as Alzheimer's disease, Parkinson's disease, type II diabetes, heart failure, osteoarthritis, macular degeneration, and aging of the immune system, known as immunosenescence. This is also true for medical conditions resulting from damage to cells due to acute disease, such as trauma, infarction and burns. We believe that replacing damaged or malfunctioning cells with fully functional ones may be a useful therapeutic strategy in treating many of these diseases and conditions.

A stem cell is a cell that has the ability to branch out and change, or differentiate, into two or more different cell types. Stem cells are self-renewing primitive cells that have the ability to develop into functional, differentiated cells. In general, there are two broad categories of stem cells: adult stem cells and embryonic stem cells. Adult stem cells are derived from various tissues in the human body. Because they can branch out into many different cell types, they are referred to as "multipotent." Multipotent means these cells develop into multiple, but not all, types of cells in the body.

Embryonic stem cells, referred to as ES cells, which are derived from pre-implantation embryos, are unique because they are "pluripotent," which means that they can develop into all cells and tissues in the body, and they self-renew indefinitely in their undifferentiated state. The ability of ES cells to divide indefinitely in the undifferentiated state without losing pluripotency is a unique characteristic that distinguishes them from all other stem cells discovered to date in humans.

Our business is focused on both the development and commercialization of adult stem cell transplantation therapies and ES cell based technologies.

Our adult stem cell-based products are specifically targeted at therapies for heart and other cardiovascular disease and are at a more advanced stage of development than our human ES cell based technologies. Our first human ES cell-based product retinal pigmented epithelial cells are poised to enter Phase I clinical trials pending clearance by the FDA. We believe retinal pigmented epithelial cells technologies have potentially broader and more powerful applications with respect to a wide range of diseases.

### Human ES Cell Programs

Since the discovery of the human ES cell, medical researchers worldwide have generally recognized the significance of this new technology and have begun to focus research on the translation of this discovery into important new therapies. Specifically, researchers have focused on several key challenges including:

- isolating and purifying cell lines,
- growing stable cell lines in culture for long periods without mutations,
- manufacturing cell lines in numbers sufficient for therapy,
- differentiating ES cells into all of the cell types desired for therapies, and
- solving the potential rejection of ES cells used in therapies due to immuno-incompatibility with the patient.

We believe that solving the potential rejection of ES cells in patients is the greatest scientific obstacle to developing successful therapeutics. Our research and technologies are focused on solving this obstacle by creating stem cell therapeutics with compatible tissues. Compatible tissues are referred to as being histocompatible.

We believe the potential markets for regenerative medicine and stem cell therapy are large. The table below summarizes the potential United States patient populations which we believe may be amenable to cell or organ transplantation and represent target markets for products generated through our regenerative medicine technology.

### POTENTIAL U.S. PATIENT POPULATIONS FOR CELL-BASED THERAPIES

[chart format]

Medical Condition	Number of Patients*
Cardiovascular disease	70 million *
Autoimmune disease	50 million *
Diabetes	18 million
Osteoporosis	10 million
Cancer	10 million
Alzheimer's disease	4.5 million
Parkinson's disease	1 million
Burns (severe)	1.1 million
Spinal-cord injuries	0.25 million
Birth defects	0.15 million/year

\* These estimates are based on patient estimates published by the following organizations from April 2005 to the present: the American Heart Association, the American Autoimmune Related Diseases Association, SEER (Surveillance, Epidemiology and End Result), American Burn Association, March of Dimes, the Alzheimer's Association, the Alzheimer's Disease Education & Referral Center (National Institute on Aging), the National Institutes of Health's National Institute on Neurological Disorders and Stroke, the Foundation for Spinal Cord Injury Prevention, Care & Cure, the Centers for Disease Control and Prevention, the American Association of Diabetes Educators, the Northwest Parkinson's Foundation and the Parkinson's Action Network.

### *Our Human Embryonic Stem Cell Technologies*

The ability to produce embryonic stem cells that are immunologically compatible with the patient is the hallmark and the strength of our technology platform. We believe our technology platform will enable the transformation of a patient's cells into an embryonic state where those cells can be differentiated into specific therapeutically relevant cell types that are genetically identical to the patient. We believe our technology may also enable the production of stem cell lines, from sources external to the patient, that have a sufficiently high level of histocompatibility to be useful in making cell therapies readily accessible to a large segment of the patient population, without the need for exact genetic matching of tissues.

As a result, our technology avoids reliance on more limited approaches that involve use of cell lines that are not histocompatible with the recipient, or therapies based upon use of adult stem cells.

The use of human embryonic stem cells gives rise to ethical, legal and social issues previously rooted in the fact that ES-cell derivation deprives preimplantation embryos of the potential to develop into a human being. We have developed a method to derive human embryonic stem cell lines at the blastomere stage that does not result in the destruction of the preimplantation embryo.

In August 2001, then-President George Bush set guidelines for federal funding of research on embryonic stem cells from human embryos created by in-vitro fertilization, referred to as IVF, limiting funding to just 60 lines. IVF-ES cells have the drawback that they are not genetically matched to the recipient patient. These ES cells are allogeneic. The word allogeneic literally means "other DNA type." Therapies using allogeneic cell lines can result in immune system incompatibilities where the host immune system attacks and rejects the transplanted cells or the transplanted cells attack the host. These incompatibilities may be partially suppressed with powerful immunosuppressive drugs, but the side effects can be severe and result in life-threatening complications. As a result, these incompatibilities have the potential to generate significant inefficiencies in the application of cell therapies.

However, in March 2009, President Barack Obama issued an executive order opening the door to a significant increase in federal funding for ES cell research. That led to the National Institutes of Health (NIH) approval of 13 additional stem cell lines for use in agency-funded research. The NIH is considering whether to approve an additional 96 lines, including blastomere derived lines we submitted for consideration.

The strategic focus of our human ES cell technology is to produce cell lines that are both histocompatible with the patient and pluripotent. We have numerous proprietary technologies that we believe will generate histocompatible, pluripotent stem cells for patient-specific application. These cells maximize the potential for effective use as transplants to replace diseased or destroyed cells in human patients. If successfully developed, our cellular reprogramming technologies will make it possible to produce cells that have the proliferative capacity of young cells, have specific therapeutic application, and are immunologically compatible with the patient.

All of our ES cell technologies are at the level of basic research or in the pre-clinical stage of development.

### *Our ES Cell Research Programs*

Our ES cell research programs are divided into three core categories: cellular reprogramming, our reduced complexity program, and stem cell differentiation. Each of these core areas of focus is discussed below.

#### **I. Cellular Reprogramming**

This research program involves development of therapies based on the use of genetically identical pluripotent stem cells generated by our cellular reprogramming technologies. These technologies can be used to generate patient-specific pluripotent cells and tissues for transplantation. We believe our technology platform will enable the transformation of a patient's cells into pluripotent ES cells that are histocompatible with the patient and have the potential to be differentiated into any of the over 200 different human cell types that may be therapeutically relevant in treating diseased or destroyed tissues in human patients. We expect that our cellular reprogramming technologies will offer a new avenue for the introduction of targeted genetic modifications in cells and for the regeneration of cell lifespan, thereby making youthful cells available for aging patients. The combination of these advances, the ability to produce young cells of certain kinds that are histocompatible with the patient, is a core potential application of our technology. We believe these cellular reprogramming technologies will be effective therapies where there is time to prepare customized therapy through reprogramming of the patient's own cells.



Some of the technologies that support our cellular reprogramming program are somatic cell nuclear transfer, chromatin transfer, factor reprogramming, and fusion technologies.

Somatic cell nuclear transfer (SCNT) refers to the process wherein a body cell is transferred to an egg cell from which the nuclear DNA has been removed. This results in the body cell being "reprogrammed" by the egg cell. This reprogramming transforms the cell from the type of cell it was, for instance a skin cell, into an embryonic cell with the power to become any cell type in the body. A related technology is called chromatin transfer. Through this technology, the DNA and attached proteins, or chromatin, of the somatic cell is reprogrammed prior to transfer into an egg cell. Chromatin transfer has the potential to improve the efficiencies and therefore reduce the cost of nuclear transfer. We believe that one critical advantage of our proprietary SCNT and chromatin transfer technologies is that the cells are "rejuvenated" by returning the cell to a youthful state. This is important because these youthful cells will have the proliferative capacity of young cells. These healthy replacement cells, which would be genetically identical to the patient's own cells, would then be used for cell transplantation.

Our fusion technologies involve the fusion of the cytoplasm of one cell into another. In the same manner that the cytoplasm of an egg cell is capable of transforming any cell back to an embryonic state, the fusion of the cytoplasm of other cell types, including differentiated cell types (such as blood cells) is capable of reprogramming another cell type, such as a skin cell. These technologies have the potential of transforming a cell from a patient into another medically-useful cell type also identical to the patient. They also have the potential to fuse the cytoplasm of undifferentiated cells, such as embryonic stem cells, with somatic cells to transport the somatic cell DNA back to pluripotency. Alternatively, factors expressed by embryonic stem cells can be introduced into somatic cells to induce pluripotency. We believe that the fusion and factor reprogramming technologies we are developing can be developed into as broad and powerful techniques as SCNT, producing histocompatible, youthful stem cells that are multi and potentially even pluripotent. If successfully developed, this technology may also provide a pathway that does not utilize human egg cells which would reduce the cost of the procedure and increase the number of patients that could benefit from its implementation.

## II. Stem Cell Differentiation

Regenerative medicine requires that stem cells, from whatever source derived, be differentiated, or re-differentiated, into specific body cell types and then physically transplanted into a patient. Differentiation into tissues such as cardiac muscle, blood, and other tissues occurs spontaneously in ES cells being cultured in a dish. Successful application of stem cell technology will require control over the specific kinds of cells into which stem cells differentiate. Control of differentiation and the culture and growth of stem and differentiated cells are important current areas of research for us. Also, some chemicals, such as retinoic acid, can be used to trigger differentiation into specific cell types such as nerve cells. We intend to pursue differentiation approaches both in-house and through collaborations with other researchers who have particular interests in, and skills related to, cellular differentiation. These efforts include using both animal and human stem cell lines. Our research in this area includes projects focusing on developing many different cell types that may be used in the future to treat a wide range of diseases. Our researchers have generated stable retinal pigment epithelium, or RPE, cell lines for use in our clinical retinal program and are working on projects to generate stable cell lines with particular focus on blood lineage and vascular epithelial cell lines from hemangioblast cells.

*Retinal Pigment Epithelium Program.* In November, 2006 we published data demonstrating human ES cell-derived RPE cells were capable of rescuing visual function in Royal College of Surgeon rats. Following the publication of that data, we entered into a pre-clinical development collaboration with Casey Eye Institute at Oregon Health & Science University. The purpose of the collaboration was to conduct dosage and safety studies in preparation for IND and Phase I human clinical trials. As mentioned, in November of last year we filed an Investigational New Drug (IND) Application with the US Food and Drug Administration (FDA) to initiate a Phase I/II multicenter study using embryonic stem cell derived retinal cells to treat patients with Stargardt's Macular Dystrophy (SMD).

**Hemangioblast Program.** Hemangioblasts are a newly-characterized stem cell capable of differentiating into both hematopoietic, meaning blood cell-forming, and angiogenic, meaning blood vessel endothelium-forming, cells. We believe it will be possible to utilize hemangioblast cells in engraftment to repair age-related endothelial dysfunction associated with numerous significant age-related diseases, including cardiovascular disease, stroke, and perhaps even cancer. In 2006 we successfully derived hemangioblast cells generated from the company's blastomere-derived human embryonic stem cell lines. In 2007, we published data reporting that through utilization of hemangioblast based therapy we generated function *in vivo* with respect to the repair of ischemic retinal vasculatures and restoration of blood flow in ischemic limbs. In addition, we also reported increased survival rates of animals suffering from myocardial infarction. The hemangioblast program is currently in preclinical development.

### III. Adult Stem Cell Program

Our adult stem cell-based program is developing an autologous myoblast transplantation therapy delivered using a minimally invasive catheter injection system to restore cardiac function in patients with advanced heart disease. The key target for the therapy will be heart failure patients with New York Heart Association ("NYHA") scores Class II to IV. The company's therapy could also benefit patients supported on ventricular assistance devices and potential additional indications, such as acute myocardial infarction, peripheral artery disease, and non-cardiac tissue repair. Currently available treatment options for heart failure patients are inadequate and can only slow the progression of heart failure; none can halt or reverse the process. We believe our autologous myoblast transplantation therapy uses patented myoblast compositions for catheter delivery to the heart offering repair of the disease in heart failure patients and for those end-stage disease patients on ventricular assistance device support.

These indications represent a significant unmet medical need and hold significant potential for clinical approval.

Our transplantation therapy involves extraction through simple biopsy from a patient's thigh of myoblasts, which are non-embryonic, skeletal muscle stem cells, that can be expanded in culture and injected back into damaged and scarred regions of the heart. This therapy promotes repair of damaged cardiac tissue by autologous cells, thereby avoiding immune rejection as each patient receives their own cells. Skeletal muscle, unlike heart muscle, can repair itself after injury. Skeletal muscle contains immature myoblasts that can fuse with surrounding myoblasts or with damaged muscle fibers to regenerate contractile skeletal muscle. In experimental models, our researchers have demonstrated that skeletal myoblasts can be transplanted into an infarcted myocardium with the subsequent development of elongated, striated cells characteristic of both skeletal and cardiac muscle. Our Phase I clinical studies have demonstrated the efficacy of this therapy on a preliminary basis.

We have received FDA approval to proceed with our Phase II clinical trial, to evaluate the applications for myoblast transplantation in slowing and/or reversing the impact of heart failure.

We perform our myoblast expansion, packaging, shipment, and quality testing using proprietary procedures that adhere to GMP regulations for manufacturing clinical trial material. After expansion, the myoblasts are packaged and delivered to the clinical site for implantation into the injured heart tissue by a surgeon or interventional cardiologist. To maximize cell therapy effectiveness, adequate numbers of cells must be delivered to the site of damage in a repeatable and safe manner. Our therapy utilizes a minimally invasive catheter-based delivery methodology, which provides a safe, targeted and high efficiency approach to cell delivery to the infarct area.

We believe that, unlike currently available treatment options, myoblast therapy has the ability to repair and improve the function of a damaged heart.

Our preclinical and Phase I clinical studies support the conclusion that our therapy presents significant advantages over currently available treatments, including:

- Ability to restore cardiac function through new muscle formation
- Ability to prevent further decline of heart function
- No risk immunological rejection of myoblasts due to autologous nature of the therapy
- Complementary to and capable of improving outcomes of current therapeutic options for heart disease
- hematopoietic cells for blood diseases and cancer,
- myocardial and endothelial vascular tissue for cardiovascular disease,
- congestive heart failure, myocardial infarction and other cardiovascular disease
- skin cells for dermatological conditions,
- retinal pigment epithelium cells as treatment for macular degeneration and retinal pigmentosis,
- neural cells for spinal cord injury, Parkinson's disease and other neuro-degenerative diseases,
- pancreatic islet  $\beta$  cells for diabetes,
- liver cells for hepatitis and cirrhosis,
- cartilage cells for arthritis, and
- lung cells for a variety of pulmonary diseases.

#### **Potential Commercial Applications of our ES Cell and Adult Stem Cell Technologies**

We believe that, if successfully developed, stem cell-based therapy has the potential to provide treatment for a broad range of acute and chronic degenerative diseases. We believe the potential applications of cell-based therapeutics include

While we expect that any future products will take the form of medical procedures, tangible therapeutics, or combinations thereof, we currently have no products, and the identity of our future products, if any, is dependent upon the results of our ongoing research efforts, and, therefore cannot be determined at this time.

#### ***Our Intellectual Property***

Our research and development is supported by a broad intellectual property portfolio. We currently own or have exclusive licenses to over 45 patents and have over 170 patent applications pending worldwide in the field of regenerative medicine and stem cell therapy. We also have non-exclusive rights to a portfolio of patents and patent applications that support our core intellectual property.

Our success will likely depend upon our ability to preserve our proprietary technologies and operate without infringing the proprietary rights of other parties. However, we may rely on certain proprietary technologies and know-how that are not patentable. We protect such proprietary information, in part, by the use of confidentiality agreements with our employees, consultants and certain of our contractors.

We maintain a disciplined patent policy and, when appropriate, seek patent protection for inventions in our core technologies and in ancillary technologies that support our core technologies or which we otherwise believe will provide us with a competitive advantage. We pursue this strategy by filing patent applications for discoveries we make, either alone or in collaboration with scientific collaborators and strategic partners. Typically, although not always, we file patent applications both in the United States and in select international markets. In addition, we plan to obtain licenses or options to acquire licenses to patent filings from other individuals and organizations that we anticipate could be useful in advancing our research, development and commercialization initiatives and our strategic business interests.

The following table identifies the issued patents we own or license that we believe currently support our technology platform.

**Owned by Advanced Cell Technology, Inc.**

Number Patent	Country	Filing Date	Issue Date	Expiration Date*	Title
6,808,704	United States (US)	09/06/2000	10/26/2004	09/6/2020	Method for Generating Immune-Compatible Cells and Tissues Using Nuclear Transfer Techniques
783162	Australia (AU)	09/06/2000	01/12/2006	09/6/2020	Method for Generating Immune-Compatible Cells and Tissues Using Nuclear Transfer Techniques
265679	Mexico	09/06/2000	04/03/2009	09/06/2020	Method for Generating Immune-Compatible Cells and Tissues Using Nuclear Transfer Techniques
536786	New Zealand (NZ)	09/06/2000	01/11/2007	09/6/2020	Method for Generating Immune-Compatible Cells and Tissues Using Nuclear Transfer Techniques
782385	AU	10/13/2000	11/3/2005	10/13/2020	Method of Differentiation of Morula or Inner Cell Mass Cells and Method of Making Lineage-Defective Embryonic Stem Cells
518191	NZ	10/13/2000	05/10/2004	10/13/2020	Method of Differentiation of Morula or Inner Cell Mass Cells and Method of Making Lineage-Defective Embryonic Stem Cells
516236	NZ	06/30/2000	08/07/2005	06/30/2020	Cytoplasmic Transfer to De-Differentiate Recipient Cells
782286	AU	06/30/2000	10/27/2005	06/30/2020	Cytoplasmic Transfer to De-Differentiate Recipient Cells
531844	NZ	09/06/2000	12/08/05	09/06/2020	Telomere Restoration and Extension of Cell Life-Span in Animals Cloned from Senescent Somatic Cells
519347	NZ	12/20/2000	11/11/2004	12/20/2020	Method to Produce Cloned Embryos and Adults from Cultured Cells
00818200.0	China (CN)	12/20/2000	10/18/2006	12/20/2020	Method to Produce Cloned Embryos and Adults from Cultured Cells
5,453,366	US	03/15/1993	09/26/1995	09/26/2012	Method of Cloning Bovine Embryos
6,011,197	US	01/28/1999	01/04/2000	03/06/2017	Method of Cloning Bovines Using Reprogrammed Non-Embryonic Bovine Cells
6,395,958	US	07/15/1999	05/28/2002	03/06/2017	Method of Producing a Polypeptide in an Ungulate
5,496,720	US	02/10/1993	03/05/1996	03/05/2013	Parthenogenic Oocyte Activation
5,843,754	US	06/06/1995	12/01/1998	12/01/2015	Parthenogenic Bovine Oocyte Activation
6,194,202	US	03/04/1996	02/27/2001	02/10/2013	Parthenogenic Oocyte Activation
6,077,710	US	10/21/1998	06/20/2000	02/10/2013	Parthenogenic Oocyte Activation
5,346,990	US	03/12/1991	09/13/1994	09/13/2011	Sex-Associated Membrane Proteins and Methods for Increasing the Probability that Offspring will be of a Desired Sex

**Owned by Advanced Cell Technology, Inc.'s wholly-owned subsidiary Mytogen, Inc.**

Number Patent	Country	Filing Date	Issue Date	Expiration Date*	Title
6,673,604	US	07/24/2000	01/06/2004	07/24/2020	Muscle Cells and Their Use in Cardiac Repair**
6,432,711	US	11/01/1994	08/13/2002	08/13/2019	Embryonic Stem Cells Capable of Differentiating into Desired Cell Lines
2,174,746	Canada	11/02/1994	04/24/2007	11/02/2014	Embryonic Stem Cells Capable of

(CA)

Differentiating into Desired Cell Lines

\*\* Currently undergoing Inter Partes Reexamination

University of Massachusetts Exclusive License to Advanced Cell Technology, Inc.

Number Patent	Country	Filing Date	Issue Date	Expiration Date*	Title
518365	NZ	10/27/2000	08/12/2004	10/27/2020	Gynogenetic or Androgenetic Production of Pluripotent Cells and Cell Lines, and Use Thereof to Produce Differentiated Cells and Tissues
782846	AU	10/27/2000	12/15/2005	10/27/2020	Gynogenetic or Androgenetic Production of Pluripotent Cells and Cell Lines, and Use Thereof to Produce Differentiated Cells and Tissues
5994619	US	12/16/1996	11/30/1999	04/01/2016	Production of Chimeric Bovine or Porcine Animals Using Cultured Inner Cell Mass Cells
5905042	US	04/01/1996	05/08/1999	04/01/2016	Production of Chimeric Bovine or Porcine Animals Using Cultured Inner Cell Mass Cells

\* Actual patent expiration dates may differ from the dates listed herein including due to patent term adjustments pursuant to 35 U.S.C. § 154(b) and 37 C.F.R. §§ 1.702-1.705.

The fundamental consequence of patent expiration is that the invention covered by that patent will enter the public domain. However, the expiration of patent protection, or anticipated patent protection, for the bulk of our portfolio is not scheduled to begin for approximately ten to fifteen years. Due to the rapid pace of technology development in this field, and the volume of intellectual property we anticipate will be generated over the next decade, it is unlikely that the expiration of any existing patents or patent rights would have an adverse effect on our business. Due to our current stage of development, our existing patent portfolio is not currently supporting a marketed product, so we will not suffer from any reduction in product revenue from patent expiration. Any actual products that we develop are expected to be supported by intellectual property covered by current patent applications that, if granted, would not expire for 20 years from the date first filed. For example, our patent rights under the University of Massachusetts license listed in the patent table, above, do not begin to expire until 2016. Due to the early stage of our business, we differ from, for example, the pharmaceutical industry where the loss of a key significant patent can result in contemporaneous loss of products, programs or revenues. As our table demonstrates, our business is at the front end of the patent protection spectrum and is not expected to be significantly impacted by expiration of existing patents or patents issued in response to existing applications.

#### ***Research and License Agreements***

##### **Licenses of Intellectual Property to Us**

The following summarizes technology licensed to us.

***UMass License*** - On February 1, 2002 and April 16, 1996, we entered into exclusive license agreements (indefinite license period) with the University of Massachusetts. The 1996 Agreement has been amended by amendments dated September 1, 1997, May 31, 2000 and September 19, 2002. Pursuant to these agreements, the University of Massachusetts, referred to as UMass, exclusively licensed to us certain biological materials, patent rights and related technology for commercialization in specified fields. The license agreements require us to use diligent efforts to develop licensed products and licensed services and require us to pay certain royalties, minimum annual royalties, milestone payments and sublicense income to UMass. UMass received 73,263 shares of common stock of ACT as partial consideration of the license granted. We are currently behind on our payments of all UMass license fees, since 2008, and as such we are in breach of the license agreement.

***2002 License*** - Under the 2002 license, UMass licenses to us certain patent rights relating to the cloning of non-human animals for use in connection with the development, manufacture and sale of products and services in the field of non-human animals for agriculture, companion animals, research and diagnostic products, non-human and human therapeutics, and neutraceuticals, except production of immunoglobulin in the blood of *Bos taurus* and *Bos indicus*. We are required to pay royalties to UMass ranging from 1.5% to 2.0% based on the covered product or service. We agreed to pay minimum royalty payments of \$15,000 on the first and second anniversary of the agreement, \$20,000 on the third anniversary, \$25,000 on the fourth anniversary, and increasing to \$45,000 on the fifth anniversary and for each year thereafter. We also agreed to make milestone payments to UMass of up to \$1,630,000 upon the achievement of various development and commercialization milestones. Finally, we have agreed to pay UMass 18% of all sublicense income.

***1996 License*** - The 1996 license covers certain patent rights, biological materials and know-how related to the cloning of non-human animals and cells for use in cell fields except the production of immunoglobulin in the blood of *Bos taurus* and *Bos indicus*. We are required to pay royalties ranging from 2.5% to 4.5% on net sales of products and services covered by the license, and minimum royalty payments in the amount of \$15,000 per year (beginning on the later of the fourth year after the effective date of the agreement or the completion of certain clinical trials) for net sales on products and services for use in human therapeutics, and \$30,000 per year (beginning in the third year after the effective date of the agreement) for net sales on products and services for all uses other than in human therapeutics. UMass agreed to waive minimum royalty payments during any calendar year in which we fund research at UMass in the aggregate amount of \$300,000. There are no milestone payments. We agreed to pay UMass 18% of all sublicense income except for equity. With respect to equity, we are required to pay UMass an amount equal to 10% of the total equity we receive for any transfer of rights under the 1996 license.



Both the 2002 agreement and the 1996 agreement remain in effect until all issued patents within the patent rights licensed under the agreement have expired, or for a period ten years after the effective date of the agreement if no patents have issued within that ten-year period. Each party has the right to terminate the agreement upon the occurrence of a material uncured breach. We also have the right to terminate at any time for any reason with ninety days' written notice.

**Wake Forest License** - On January 26, 2001, we entered into a materials and research data license agreement with Wake Forest University (indefinite license period), pursuant to which WFU granted to us a worldwide, exclusive, royalty-free, perpetual and irrevocable right and license to use certain data and stem cells and stem cell cultures created by us from biological materials provided by WFU to us for specified purposes only. The agreement allows us to utilize certain primate skin cells and ovary materials produced by WFU and transferred to us pursuant to an agreement relating to the transfer of biological materials. There are no milestone payments. There are no royalty requirements unless we desire to negotiate a commercial license for use of the biological materials provided to us by WFU. WFU received 60,000 shares of common stock of ACT Group, Inc., a now dissolved Delaware corporation referred to hereinafter as ACT Group. We have agreed to provide WFU samples of stem cells for WFU's research, education and teaching purposes and we have a first option to obtain an exclusive license to any intellectual property rights claimed by WFU in connection with the use of such stem cells. The term of the license granted is perpetual and irrevocable absent a breach by us.

**Start Licensing License** - On August 30, 2006, we entered into a Settlement and License Agreement with UMass and Start Licensing, Inc. (indefinite license period). Pursuant to this agreement Start Licensing licenses to us, on a nonexclusive, royalty-free and paid-up basis, certain patent rights for use with non-human animal research or studies, including preclinical trials, in connection with the research, development and sale of therapeutic and diagnostic human cell products.

**GenVec Agreement** - On December 28, 2005, Mytogen and GenVec, Inc. entered into a patent assignment and security agreement (indefinite period). Under the agreement, as amended on July 31, 2007, GenVec assigned certain agreements and intellectual property to Mytogen, and retained a royalty-free non-exclusive license, with the right to grant sublicenses, to practice the intellectual property in connection with products, processes or services developed or provided by GenVec other than autologous and allogenic skeletal myoblasts for cardiac therapy. Under the original agreement, Mytogen granted a security interest in the assigned intellectual property, but the security interest was released in the amendment to the agreement. Under the agreement, as amended, Mytogen must use commercially reasonable efforts to commercialize the assigned intellectual property, including by spending specified amounts in support of research and development in support of such commercialization; Mytogen must pay GenVec one-half of the first milestone payment (anticipated to be two million U.S. dollars) received by Mytogen under the Terumo Agreement; and Mytogen must also pay GenVec four percent (4%) of the net sales revenue from sales or other provision of products, processes or services covered by the agreement.

#### **Exclusive Licenses of Intellectual Property by Us**

The following summarizes licenses from us to third parties.

**Exeter Life Sciences License** - On October 22, 2003, we entered into an exclusive license with Exeter Life Sciences, Inc. (indefinite license period), pursuant to which we exclusively licensed to Exeter certain technology and patent rights for use in the fields of agriculture, endangered species, companion animals and equine animals. The license also grants Exeter a right of first negotiation to any improvement patents that are obtained by us that relate to the licensed intellectual property or which are useful, necessary or required to develop or manufacture certain animals, cells or tissues within the defined fields of use.

Under the agreement, we license rights to certain patent rights and technology useful for the fields of use of non-human animals for agriculture, endangered animals and companion animals; excluding production of such animals for the primary purpose of producing human and non-human animal therapeutics and human healthcare products, including without limitation the production of biopharmaceutical agents in milk, such as proteins, peptides and polypeptides for pharmaceutical, nutraceutical or other use, and excluding the production of immunoglobulin in the blood of *Bos taurus* and *Bos indicus*. The field includes:

- the cloning, development, manufacture and sale of cloned non-human animals, including without limitation, bovine, hircine, ovine, porcine, equine animals and ungulates (as well as any transgenic variance or enhancements thereto) or products that are composed of, made in or derived, extracted or isolated from cells or tissues of such animals for the production of food or fiber, and the rendering of services or uses that relate to the production of such products;
- the cloning, development, manufacture and sale of endangered species for purposes of researching, aiding, reproducing or assisting in the reproduction of such endangered species;
- the cloning, development, and sale of hircine, ovine, feline, canine and equine animals (as well as any transgenic variance or enhancements thereto) for personal, business or commercial purposes, specifically excluding the sale of these animals as scientific research laboratory subjects; and
- the cloning, development, manufacture and sale of cloned equine animals (as well as any transgenic variance or enhancements thereto) or products that are composed of, made in or derived, extracted or isolated from cells or tissues of such animals for non-therapeutic purposes, including but not limited to, for use in agriculture, for use as food, for use as companion, service, work or recreational animals, or for use as racing or other equine event animals, and the rendering of services or uses that relate to the production of such products.

In consideration of the rights and licenses granted to Exeter, Exeter paid to us an initial license fee of \$1,000,000, and has agreed to pay royalties equal to 5% of the net sales of all products and services covered by the license; provided that, sublicense income for license products that are the progeny of cloned animals covered by the license or products obtained from such progeny, the royalty is 3%. Exeter is required to pay an annual maintenance fee for the license, equal to \$100,000 in 2005, increasing annually by \$50,000 up to \$500,000. Exeter's obligation to pay the annual maintenance fee was suspended until certain intellectual property that is the subject of litigation, namely the matter styled *University of Massachusetts v. James M. Robl and Phillipe Collas*, Massachusetts Superior Court, Suffolk County, Docket No. 04-0445-BLS, was settled in dispute. Negotiations are continuing to amend the license subject to the outcome of the settlement. The license also provides that we will refund certain amounts to Exeter if certain conditions concerning the referenced litigation are not met and that we will extend to Exeter rights associated with "improvement patents" that are obtained by us or the University in connection with the referenced litigation or any patent interference or opposition proceedings involving us that relate to the licensed intellectual property or which are useful, necessary or required to develop or manufacture cloned and/or transgenic non-human animals and cloned and/or transgenic cells and tissues from non-human animals within the field of use. The license grants Exeter a right of first negotiation to any improvement patents. There are no milestone payments. Exeter agrees to pay us a total of 25% of all sublicense income under the license. Either party may terminate the agreement in the event of an uncured breach. Exeter may terminate without cause on 60 days' prior written notice to us, or may terminate immediately in the event of a change in law that materially affects Exeter's ability to commercialize the licensed intellectual property under the license.

We expect that the Exeter Life Science License will be amended as a result of the Start Settlement and the settlement of the *University of Massachusetts and Advanced Cell Technology, Inc. v. Roslin Institute (Edinburgh), Geron Corporation and Exeter Life Sciences, Inc.*, U.S. District Court for the District of Columbia (Case No. 1:05-cv-00706 RMU), and *University of Massachusetts and Advanced Cell Technology, Inc. v. Roslin Institute (Edinburgh), Geron Corporation and Exeter Life Sciences, Inc.*, U.S. District Court for the District of Columbia (Case No. 1:05-cv-00353 RMU).



*Lifeline License* - On May 14, 2004, we entered into three license agreements (indefinite license periods) with Lifeline Cell Technology, formerly known as PacGen Cellco, LLC; the licenses were subsequently amended in August 2005. Pursuant to the license agreements, as amended, we licensed to Lifeline, on an exclusive or non-exclusive basis, as applicable, certain know-how and patent rights for, among other things, the research, development, manufacture and sale of human cells for cell therapy in the treatment of human diabetes and liver diseases, and retinal diseases and retinal degenerative diseases. The license agreements require milestone payments up to \$1.75 million in the aggregate. The agreement requires Lifeline to meet minimum research and development requirements. The licenses continue until expiration of the last valid claim within the licensed patent rights. Either party may terminate the agreements for an uncured breach, and Lifeline may terminate the agreement at any time with 30 days' notice.

*Exclusive License Agreement Number 1, as amended, covers patent rights and technology developed by us that are relevant to:*

- the research, development, manufacture and sale of human and non-human animal cells for commercial research and
- the manufacture and selling of human cells for therapeutic and diagnostic use in the treatment of human diabetes and liver diseases, and retinal diseases and retinal degenerative diseases.

Lifeline has agreed to pay us royalties ranging from 3% to 10% on net sales of products and services covered by the license, and a minimum royalty fee of \$175,000 in the first year, plus, commencing 12 months after the effective date of the agreement, additional minimum royalty fees in the amount of \$15,000 at 12 months, \$37,500 at 24 months, \$60,625 at 36 months, and \$75,000 annually thereafter. Lifeline also agreed to pay a license fee in the amount of \$225,000 in the form of a Convertible Promissory Note, which was repaid in cash in 2007.

We expect that Lifeline Exclusive License Agreement Number 1, as amended, will be further amended as a result of the Start Settlement and the settlement of *University of Massachusetts and Advanced Cell Technology, Inc. v. Roslin Institute (Edinburgh), Geron Corporation and Exeter Life Sciences, Inc.*, U.S. District Court for the District of Columbia (Case No. 1:05-cv-00706 RMU), and *University of Massachusetts and Advanced Cell Technology, Inc. v. Roslin Institute (Edinburgh), Geron Corporation and Exeter Life Sciences, Inc.*, U.S. District Court for the District of Columbia (Case No. 1:05-cv-00353 RMU).

*Exclusive License Agreement Number 2, as amended, covers patent rights and technology developed by UMass relevant to:*

- the research, development, manufacture and sale of human and non-human animal cells and defined animal cell lines for commercial research,
- the manufacture and selling of human cells for therapeutic and diagnostic use in the treatment of human diabetes and liver diseases and retinal diseases and retinal degenerative diseases, and
- the use of defined animal cell lines in the process of manufacturing and selling human cells for therapeutic and diagnostic use in the treatment of human diabetes and liver diseases.

Lifeline is required to pay us royalties ranging from 3% to 12% on net sales of products and services covered by the license, and a minimum royalty fee of \$100,000 in the first year, plus, commencing 12 months after the effective date of the agreement, additional minimum royalty fees in the amount of \$15,000 at 12 months, \$30,000 at 24 months, \$45,000 at 36 months, and \$60,000 annually thereafter. Lifeline also paid a license fee in the amount of \$150,000 on June 1, 2007.

We expect that Lifeline Exclusive License Agreement Number 2, as amended, will be further amended as a result of the Start Settlement and the settlement of *University of Massachusetts and Advanced Cell Technology, Inc. v. Roslin Institute (Edinburgh), Geron Corporation and Exeter Life Sciences, Inc.*, U.S. District Court for the District of Columbia (Case No. 1:05-cv-00706 RMU), and *University of Massachusetts and Advanced Cell Technology, Inc. v. Roslin Institute (Edinburgh), Geron Corporation and Exeter Life Sciences, Inc.*, U.S. District Court for the District of Columbia (Case No. 1:05-cv-00353 RMU).

*Exclusive License Agreement Number 3, as amended, covers patent rights and technology developed by Infigen relevant to the research, development, manufacture and sale of human cells for cell therapy in the treatment of therapeutic and diagnostic use in the treatment of human diabetes and liver diseases, and retinal diseases and retinal degenerative diseases.* Lifeline is required to pay us royalties equal to 6% of net sales of products and services covered by the license, and a minimum royalty fee of \$25,000 in the first year, plus, commencing 12 months after the effective date of the agreement, additional minimum royalty fees in the amount of \$7,500 at 12 months, \$7,500 at 24 months, \$6,875 at 36 months, and \$15,000 annually thereafter. Lifeline also paid a license fee in the amount of \$225,000 in cash on June 1, 2007.

We expect that Lifeline Exclusive License Agreement Number 3, as amended, will be further amended or terminated, as a result of the dissolution of Infigen and the acquisition by us of certain of the Infigen patent rights.

*Start Licensing License* - On August 30, 2006, we entered into a Settlement and License Agreement with UMass and Start Licensing, Inc. (indefinite license period). See description of this agreement above. Pursuant to this agreement, we granted Start Licensing a worldwide, exclusive, fully paid-up and royalty-free license, with the right to grant sublicenses, to certain patent rights for use in connection with all uses and applications in non-human animals. The agreement was reached in connection with the settlement of the patent interference actions. The terms of the agreement also includes an initial payment to us, which has been made, and certain milestone payments. In addition, under the agreement, Start, Geron Corporation and Roslin Institute ("Roslin") each agree not to sue us under certain patent applications owned by Roslin.

*Terumo Agreement* - Diacrin, Inc. and Terumo Corporation entered into a development and license agreement on September 4, 2002 (indefinite license period); the agreement was transferred to Mytogen on December 28, 2005. Under the agreement, the parties agreed to collaborate to develop and commercialize products in the field described as autologous skeletal myoblasts for cardiac therapy (and conditionally allogenic skeletal myoblasts for cardiac therapy) in Japan and such other Asian countries as the parties may agree. Pursuant to the agreement, Terumo has an exclusive, royalty-bearing license, with a limited right to grant sublicenses, under certain technology and patent rights controlled by Mytogen; and a non-exclusive, non-royalty bearing right and license to use certain data resulting from clinical trials for products based on the licensed technology and patent rights for purposes of seeking regulatory approvals. The agreement specifies the rights and obligations of the parties with respect to collaboration and development of products covered by the agreement. The agreement also requires Terumo to make certain milestone payments, including the following: two million dollars upon initiation of any clinical trials of any

covered product in Japan; two million dollars upon the first filing for regulatory approval of a covered product in Japan; one million dollars upon the first filing for regulatory approval of a covered product in any country other than Japan if the territory is expanded to include countries other than Japan; two million dollars upon the first commercial sale of a covered product in Japan; and one million dollars upon the first commercial sale of a covered product in any country other than Japan if the territory is expanded to include countries other than Japan. Terumo is also required under the agreement to pay royalties in an amount equal to ten percent (10%) of the net sales on covered products. In May 2008, Terumo exercised an option to extend a milestone for one year for \$300,000. The milestone consisted of a Phase I clinical trial for the Myoblast Program in Japan and was extended for two years. This agreement is no longer in effect as of December 31, 2010.

*Pharming Technologies B.V. License* - On February 26, 2008, we entered into a License Agreement with Pharming Technologies B.V., referred to as Pharming, pursuant to which we exclusively licensed to Pharming certain patents including oocyte activation patents for all uses and applications in or related to non-human animals (indefinite license period). We retained all use and applications of such patents in or related to humans. This agreement is no longer in effect as of December 31, 2010.

*Transition Holdings, Inc.* - On December 18, 2008, we entered into a license agreement with an Ireland-based investor, Transition Holdings Inc. ("Transition"), for certain of our non-core technology (indefinite license period). This license was terminated effective February 9, 2011.

*Stem Cell & Regenerative Medicine International, Inc.* - On December 1, 2008, the Company and CHA Bio & Diotech Co., Ltd. ("CHA"), a leading Korean-based biotechnology company focused on the development of stem cell technologies, formed an international joint venture. The new company, Stem Cell & Regenerative Medicine International, Inc. ("SCRMI"), will develop human blood cells and other clinical therapies based on our Hemangioblast Program, one of our core technologies. SCRMI has agreed to pay the Company fee of \$500,000 for an exclusive, worldwide, license to the Hemangioblast Program (indefinite license period).

*CHA* - On March 31, 2009, we entered into a licensing agreement (indefinite license period) under which we have licensed our retinal pigment epithelium ("RPE") technology, for the treatment of diseases of the eye, to CHA for development and commercialization exclusively in Korea. We are eligible to receive up to \$1.9 million in fees based upon achieving certain milestones, including us making an IND submission to the US FDA to commence clinical trials in humans using the technology, which we currently plan to do during the second half of 2009. We received an up-front fee of \$250,000 and additional consideration under the agreement in the amount of \$850,000. Under the terms of the agreement, CHA will incur all of the cost associated with RPE clinical trials in Korea.

*CHA* - On May 21, 2009, we have entered into a licensing agreement (indefinite license period) under which we will license our proprietary single blastomere technology, which has the potential to generate stable cell lines, including retinal pigment epithelium (RPE) cells for the treatment of diseases of the eye, to CHA for development and commercialization exclusively in Korea. We received a \$300,000 up-front license fee, and received an additional \$300,000 in December 2009. We believe there are some 200 different retinal diseases that may be impacted by this stem cell derived therapy including macular degeneration. Age-related macular degeneration (AMD) affects more than 30 million people worldwide and is the leading cause of blindness in people over 60 years of age in the United States (Source: Foundation For Fighting Blindness).

*Embryone Sciences, Inc.* - In 2008, we entered into a license agreement (indefinite license period) whereby we licensed to Embryone Sciences certain cell processing technologies, including the technology licensed from Kirin Beer. We received an up-front payment of \$470,000 and will receive royalties from future sales of product that utilizes the technologies from the licenses.

#### **Nonexclusive Licenses of Intellectual Property by Us**

We have entered into numerous nonexclusive license agreements pursuant to which we have granted non-exclusive rights to various parties to use certain patent rights in defined fields. These licenses generally provide for commercialization of our intellectual property and typically contain minimum royalties, milestones and continuing royalties based upon percentages of revenue.

#### **Regulations**

In addition to safety regulations enforced by the FDA, we are also subject to regulations under the Occupational Safety and Health Act, the Environmental Protection Act, the Toxic Substances Control Act and other present and potential future and federal, state, local, and foreign regulations.

Outside the United States, we will be subject to regulations that govern the import of drug products from the United States or other manufacturing sites and foreign regulatory requirements governing human clinical trials and marketing approval for our products. The requirements governing the conduct of clinical trials, product licensing, pricing and reimbursements vary widely from country to country.

The United States Congress, several states and foreign countries have considered legislation banning or restricting human application of ES cell-based and nuclear transfer based technologies. No assurance can be given regarding future restrictions or prohibitions that might affect our technology and business. In addition, we cannot assure you that future judicial rulings with respect to nuclear transfer technology or human ES cells will not have the effect of delaying, limiting or preventing the use of nuclear transfer technology or ES cell-based technology or delaying, limiting or preventing the sale, manufacture or use of products or services derived from nuclear transfer technology or ES cell-derived material. Any such legislative or judicial development would harm our ability to generate revenues and operate profitably.

For additional information about governmental regulations that will affect our planned and intended business operations, see "RISK FACTORS" beginning below.

#### **Employees**

As of March 11, 2011, we had 22 full-time employees, of whom six hold Ph.D. or M.D. degrees. Twelve employees are directly involved in research and development activities and ten are engaged in business development and administration. We also use the services of numerous outside consultants in business and scientific matters. We believe that we have good relations with our employees and consultants.

#### **Item 1A. RISK FACTORS**

An investment in the Company's common stock involves a high degree of risk. You should carefully consider the risks described below as well as other information provided to you in this prospectus, including information in the section of this document entitled "Forward Looking Statements." The risks and uncertainties described below are not the only ones facing us. Additional risks and uncertainties not presently known to us or that we currently believe are immaterial may also impair our business operations. If any of the following risks actually occur, our business, financial condition or results of operations could be materially adversely affected, the value of our common stock could decline, and you may lose all or part of your investment.

##### **Risks Relating to the Company's Early Stage of Development**

*Our business is at an early stage of development and we may not develop therapeutic products that can be commercialized.*

We do not yet have any product candidates in late-stage clinical trials or in the marketplace. Our potential therapeutic products will require extensive preclinical and clinical testing prior to regulatory approval in the United States and other countries. We may not be able to obtain regulatory approvals (see REGULATORY RISKS), enter clinical trials for any of our products, or commercialize any products. Our therapeutic and product candidates may prove to have undesirable and unintended side effects or other characteristics adversely affecting their safety, efficacy or cost-effectiveness that could prevent or limit their use. Any product using any of our technology may fail to provide the intended therapeutic benefits, or achieve therapeutic benefits equal to or better than the standard of treatment at the time of testing or production. In addition, we will need to determine whether any of our potential products can be manufactured in commercial quantities or at an acceptable cost. Our efforts may not result in a product that can be or will be marketed successfully. Physicians may not prescribe our products, and patients or third party payors may not accept our products. For these reasons we may not be able to generate revenues from commercial production.

*We have limited clinical testing, regulatory, manufacturing, marketing, distribution and sales capabilities which may limit our ability to generate revenues.*

Due to the relatively early stage of our therapeutic products, regenerative medical therapies and stem cell therapy-based programs, we have not yet invested significantly in regulatory, manufacturing, marketing, distribution or product sales resources. We cannot assure you that we will be able to invest or develop any of these resources successfully or as expediently as necessary. The inability to do so may inhibit or harm our ability to generate revenues or operate profitably.

*We have a history of operating losses and we may not achieve future revenues or operating profits.*

We have generated modest revenue to date from our operations. Historically we have had net operating losses each year since our inception. As of December 31, 2010, we have an accumulated deficit of \$180,949,523 and a stockholders' deficit of \$23,653,090. We incurred net losses of \$54,373,332 and \$36,758,208 for the years ended December 31, 2010 and 2009, respectively. We have limited current potential sources of income from licensing fees and the Company does not generate significant revenue outside of licensing non-core technologies. Additionally, even if we are able to commercialize our technologies or any products or services related to our technologies it is not certain that they will result in revenue or profitability.

*We are in the early stages of a strategic joint venture which may slow, impede or result in the termination of potential therapeutic products whose development is now the responsibility of the partnership and not solely of the Company.*

In 2008, we entered into a new partnership (CHA) and as a result, we are subject to 3rd party interests (see RISKS RELATED TO THIRD PARTY RELIANCE) and control issues, not the least of which relates to certain of our employees no longer being exclusively managed by us. We therefore could be at risk for losing key employees. Additionally substantial operating and working capital will be required and there is no assurance that CHA Biotech Co. limited, partner in our joint venture, will be able to fund their requirements.

*We have a limited operating history on which investors may evaluate our operations and prospects for profitable operations.*

If we continue to suffer losses as we have in the past, investors may not receive any return on their investment and may their entire investment. Our prospects must be considered speculative in light of the risks, expenses and difficulties frequently encountered by companies in their early stages of development, particularly in light of the uncertainties relating to the new, competitive and rapidly evolving markets in which we anticipate we will operate. To attempt to address these risks, we must, among other things, further develop our technologies, products and services, successfully implement our research, development, marketing and commercialization strategies, respond to competitive developments and attract, retain and motivate qualified personnel. A substantial risk is involved in investing in us because, as an early stage company we have fewer resources than an established company, our management may be more likely to make mistakes at such an early stage, and we may be more vulnerable operationally and financially to any mistakes that may be made, as well as to external factors beyond our control.

#### **Risks Relating to Technology**

*We are dependent on new and unproven technologies.*

Our risks as an early stage company are compounded by our heavy dependence on emerging and sometimes unproven technologies. If these technologies do not produce satisfactory results, our business may be harmed. Additionally some of our technologies and significant potential revenue sources involve ethically sensitive and controversial issues which could become the subject of legislation or regulations that could materially restrict our operations and, therefore, harm our financial condition, operating results and prospects for bringing our investors a return on their investment.

*Over the last two years we have narrowed our potential product pool to focusing on our Retinal Program as well as the applications of our I.P.S. technology, which will limit our revenue sources.*

Our human embryonic stem cell program is in the IND phase; our myoblast program has received FDA clearance to proceed to Phase II human clinical trials; our Hemangioblast program is in the preclinical development stage, and the Company doesn't foresee having a commercial product until clinical trials are completed. We have identified the programs that we are working to get into the clinical testing phase. We have narrowed the scope of our developmental focus to our Retinal Program and those related therapies, our blastomere program and, as part of our recently established partnership with CHA, developing products in the hemangioblast/immunology arena (see DESCRIPTION OF BUSINESS Section of prospectus). As a result of our narrower product focus we have fewer revenue sources. Our emphasis on fewer programs may hinder our results if these programs are not successful. Although our adult stem cell myoblast program has been approved for a Phase II clinical trial, we have suspended that program indefinitely due to a lack of funding. As a result of our emphasis on our retinal program, our hemangioblast program and our blastomere program, our ability to progress as a company is more significantly hinged on the success of fewer programs and thus, a setback or adverse development relating to any one of them could potentially have a significant impact on share price as well as an inhibitory effect on our ability to raise additional capital. Additionally, we partially rely on nuclear transfer and embryonic stem cell technologies that we may not be able to successfully develop, which will prevent us from generating revenues, operating profitably or providing investors any return on their investment. We cannot guarantee that we will be able to successfully develop our retinal, hemangioblast, blastomere, nuclear transfer technology, embryonic stem cell or myoblast technologies or that such development will result in products or services with any significant commercial utility. We anticipate that the commercial sale of such products or services, and royalty/licensing fees related to our technology, would be our primary sources of revenues. If we are unable to develop our technologies, investors will likely lose their entire investment in us.



*We may not be able to commercially develop our technologies and proposed product lines, which, in turn, would significantly harm our ability to earn revenues and result in a loss of investment.*

Our ability to commercially develop our technologies will be dictated in large part by forces outside our control which cannot be predicted, including, but not limited to, general economic conditions, the success of our research and pre-clinical and field testing, the availability of collaborative partners to finance our work in pursuing applications of nuclear transfer technology and technological or other developments in the biomedical field which, due to efficiencies, technological breakthroughs or greater acceptance in the biomedical industry, may render one or more areas of commercialization more attractive, obsolete or competitively unattractive. It is possible that one or more areas of commercialization will not be pursued at all if a collaborative partner or entity willing to fund research and development cannot be located. Our decisions regarding the ultimate products and/or services we pursue could have a significant adverse affect on our ability to earn revenue if we misinterpret trends, underestimate development costs and/or pursue wrong products or services. Any of these factors either alone or in concert could materially harm our ability to earn revenues or could result in a loss of any investment in us.

*If we are unable to keep up with rapid technological changes in our field or compete effectively, we will be unable to operate profitably.*

We are engaged in activities in the biotechnology field, which is characterized by extensive research efforts and rapid technological progress. If we fail to anticipate or respond adequately to technological developments, our ability to operate profitably could suffer. We cannot assure you that research and discoveries by other biotechnology, agricultural, pharmaceutical or other companies will not render our technologies or potential products or services uneconomical or result in products superior to those we develop or that any technologies, products or services we develop will be preferred to any existing or newly-developed technologies, products or services.

#### **Risks Related to Intellectual Property**

*Our business is highly dependent upon maintaining licenses with respect to key technology.*

Several of the key patents we utilize are licensed to us by third parties. These licenses are subject to termination under certain circumstances (including, for example, our failure to make minimum royalty payments or to timely achieve development and commercialization benchmarks). The loss of any of such licenses, or the conversion of such licenses to non-exclusive licenses, could harm our operations and/or enhance the prospects of our competitors.

Certain of these licenses also contain restrictions, such as limitations on our ability to grant sublicenses that could materially interfere with our ability to generate revenue through the licensing or sale to third parties of important and valuable technologies that we have, for strategic reasons, elected not to pursue directly. The possibility exists that in the future we will require further licenses to complete and/or commercialize our proposed products. We cannot assure you that we will be able to acquire any such licenses on a commercially viable basis.

*Certain of our technology is not protectable by patent.*

Certain parts of our know-how and technology are not patentable. To protect our proprietary position in such know-how and technology, we intend to require all employees, consultants, advisors and collaborators to enter into confidentiality and invention ownership agreements with us. We cannot assure you, however, that these agreements will provide meaningful protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure. Further, in the absence of patent protection, competitors who independently develop substantially equivalent technology may harm our business.

*Patent litigation presents an ongoing threat to our business with respect to both outcomes and costs.*

We have previously been involved in patent interference litigation, and it is possible that further litigation over patent matters with one or more competitors could arise. We could incur substantial litigation or interference costs in defending ourselves against suits brought against us or in suits in which we may assert our patents against others. If the outcome of any such litigation is unfavorable, our business could be materially adversely affected. To determine the priority of inventions, we may also have to participate in interference proceedings declared by the United States Patent and Trademark Office, which could result in substantial cost to us. Without additional capital, we may not have the resources to adequately defend or pursue this litigation.

*We may not be able to protect our proprietary technology, which could harm our ability to operate profitably.*

The biotechnology and pharmaceutical industries place considerable importance on obtaining patent and trade secret protection for new technologies, products and processes. Our success will depend, to a substantial degree, on our ability to obtain and enforce patent protection for our products, preserve any trade secrets and operate without infringing the proprietary rights of others. We cannot assure you that:

- we will succeed in obtaining any patents in a timely manner or at all, or that the breadth or degree of protection of any such patents will protect our interests,
- the use of our technology will not infringe on the proprietary rights of others,
- patent applications relating to our potential products or technologies will result in the issuance of any patents or that, if issued, such patents will afford adequate protection to us or not be challenged, invalidated or infringed, and
- patents will not issue to other parties, which may be infringed by our potential products or technologies.
- we will continue to have the financial resources necessary to prosecute our existing patent applications, pay maintenance fees on patents and patent applications, or file patent applications on new inventions.

We are aware of certain patents that have been granted to others and certain patent applications that have been filed by others with respect to nuclear transfer technologies. The fields in which we operate have been characterized by significant efforts by competitors to establish dominant or blocking patent rights to gain a competitive advantage, and by considerable differences of opinion as to the value and legal legitimacy of competitors' purported patent rights and the technologies they actually utilize in their businesses.

*Patents obtained by other persons may result in infringement claims against us that are costly to defend and which may limit our ability to use the disputed technologies and prevent us from pursuing research and development or commercialization of potential products.*

A number of other pharmaceutical, biotechnology and other companies, universities and research institutions have filed patent applications or have been issued patents relating to cell therapies, stem cells, and other technologies potentially relevant to or required by our expected products. We cannot predict which, if any, of such applications will issue as patents or the claims that might be allowed. We are aware that a number of companies have filed applications relating to stem cells. We are also aware of a number of patent applications and patents claiming use of stem cells and other modified cells to treat disease, disorder or injury.

If third party patents or patent applications contain claims infringed by either our licensed technology or other technology required to make and use our potential products and such claims are ultimately determined to be valid, there can be no assurance that we would be able to obtain licenses to these patents at a reasonable cost, if at all, or be able to develop or obtain alternative technology. If we are unable to obtain such licenses at a reasonable cost, we may not be able to develop some products commercially. We may be required to defend ourselves in court against allegations of infringement of third party patents. Patent litigation is very expensive and could consume substantial resources and create significant uncertainties. And adverse outcome in such a suit could subject us to significant liabilities to third parties, require disputed rights to be licensed from third parties, or require us to cease using such technology.

*We are not in full compliance with some of our license agreements.*

We are not in full compliance with some of our licenses (see Our Intellectual Property in the DESCRIPTION OF BUSINESS section of this prospectus) and due to limited financial resources we cannot guarantee that we will regain full compliance status. If we are unable to be in compliance with our license agreements, our business may be harmed.

*We may not be able to adequately defend against piracy of intellectual property in foreign jurisdictions.*

Considerable research in the areas of stem cells, cell therapeutics and regenerative medicine is being performed in countries outside of the United States, and a number of potential competitors are located in these countries. The laws protecting intellectual property in some of those countries may not provide adequate protection to prevent our competitors from misappropriating our intellectual property. Several of these potential competitors may be further along in the process of product development and also operate large, company-funded research and development programs. As a result, our competitors may develop more competitive or affordable products, or achieve earlier patent protection or product commercialization than we are able to achieve. Competitive products may render any products or product candidates that we develop obsolete.

#### **Regulatory Risks**

*We cannot market our product candidates until we receive regulatory approval.*

We must comply with extensive government regulations in order to obtain and maintain marketing approval for our products in the United States and abroad. The process of obtaining regulatory approval is lengthy, expensive and uncertain. In the United States, the FDA imposes substantial requirements on the introduction of biological products and many medical devices through lengthy and detailed laboratory and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these requirements typically takes several years and the time required to do so may vary substantially based upon the type and complexity of the biological product or medical device.

In addition, product candidates that we believe should be classified as medical devices for purposes of the FDA regulatory pathway may be determined by the FDA to be biologic products subject to the satisfaction of significantly more stringent requirements for FDA approval. Any difficulties that we encounter in obtaining regulatory approval may have a substantial adverse impact on our business and cause our stock price to significantly decline.



*We cannot assure you that we will obtain FDA or foreign regulatory approval to market any of our product candidates for any indication in a timely manner or at all.*

If we fail to obtain regulatory approval of any of our product candidates for at least one indication, we will not be permitted to market our product candidates and may be forced to cease our operations.

*Even if some of our product candidates receive regulatory approval, these approvals may be subject to conditions, and we and our third party manufacturers will in any event be subject to significant ongoing regulatory obligations and oversight.*

Even if any of our product candidates receives regulatory approval, the manufacturing, marketing and sale of our product candidates will be subject to stringent and ongoing government regulation. Conditions of approval, such as limiting the category of patients who can use the product, may significantly impact our ability to commercialize the product and may make it difficult or impossible for us to market a product profitably. Changes we may desire to make to an approved product, such as cell culturing changes or revised labeling, may require further regulatory review and approval, which could prevent us from updating or otherwise changing an approved product. If our product candidates are approved by the FDA or other regulatory authorities for the treatment of any indications, regulatory labeling may specify that our product candidates be used in conjunction with other therapies.

*Once obtained, regulatory approvals may be withdrawn and can be expensive to maintain.*

Regulatory approval may be withdrawn for a number of reasons, including the later discovery of previously unknown problems with the product. Regulatory approval may also require costly post-marketing follow-up studies, and failure of our product candidates to demonstrate sufficient efficacy and safety in these studies may result in either withdrawal of marketing approval or severe limitations on permitted product usage. In addition, numerous additional regulatory requirements relating to, among other processes, the labeling, packaging, adverse event reporting, storage, advertising, promotion and record-keeping will also apply. Furthermore, regulatory agencies subject a marketed product, its manufacturer and the manufacturer's facilities to continual review and periodic inspections. Compliance with these regulatory requirements are time consuming and require the expenditure of substantial resources.

If any of our product candidates is approved, we will be required to report certain adverse events involving our products to the FDA, to provide updated safety and efficacy information and to comply with requirements concerning the advertisement and promotional labeling of our products. As a result, even if we obtain necessary regulatory approvals to market our product candidates for any indication, any adverse results, circumstances or events that are subsequently discovered, could require that we cease marketing the product for that indication or expend money, time and effort to ensure full compliance, which could have a material adverse effect on our business.

*If our products do not comply with applicable laws and regulations our business will be harmed.*

Any failure by us, or by any third parties that may manufacture or market our products, to comply with the law, including statutes and regulations administered by the FDA or other U.S. or foreign regulatory authorities, could result in, among other things, warning letters, fines and other civil penalties, suspension of regulatory approvals and the resulting requirement that we suspend sales of our products, refusal to approve pending applications or supplements to approved applications, export or import restrictions, interruption of production, operating restrictions, closure of the facilities used by us or third parties to manufacture our product candidates, injunctions or criminal prosecution. Any of the foregoing actions could have a material adverse effect on our business.

*Our products may not be accepted in the marketplace.*

If we are successful in obtaining regulatory approval for any of our product candidates, the degree of market acceptance of those products will depend on many factors, including:

- Our ability to provide acceptable evidence and the perception of patients and the healthcare community, including third party payors, of the positive characteristics of our product candidates relative to existing treatment methods, including their safety, efficacy, cost effectiveness and/or other potential advantages,
- The incidence and severity of any adverse side effects of our product candidates,
- The availability of alternative treatments,
- The labeling requirements imposed by the FDA and foreign regulatory agencies, including the scope of approved indications and any safety warnings,
- Our ability to obtain sufficient third party insurance coverage or reimbursement for our products candidates,
- The inclusion of our products on insurance company coverage policies,
- The willingness and ability of patients and the healthcare community to adopt new technologies,
- The procedure time associated with the use of our product candidates,
- Our ability to manufacture or obtain from third party manufacturers sufficient quantities of our product candidates with acceptable quality and at an acceptable cost to meet demand, and
- Marketing and distribution support for our products.

We cannot predict or guarantee that physicians, patients, healthcare insurers, third party payors or health maintenance organizations, or the healthcare community in general, will accept or utilize any of our product candidates. Failure to achieve market acceptance would limit our ability to generate revenue and would have a material adverse effect on our business. In addition, if any of our product candidates achieve market acceptance, we may not be able to maintain that market acceptance over time if competing products or technologies are introduced that are received more favorably or are more cost-effective.

#### **Risks Related to Domestic Governmental Regulation**

*Restrictions on the use of human embryonic stem cells, and the ethical, legal and social implications of that research, could prevent us from developing or gaining acceptance for commercially viable products in these areas.*

Some of our most important programs involve the use of stem cells that are derived from human embryos. The use of human embryonic stem cells gives rise to ethical, legal and social issues regarding the appropriate use of these cells. In the event that our research related to human embryonic stem cells becomes the subject of adverse commentary or publicity, the market price for our common stock could be significantly harmed. Some political and religious groups have voiced opposition to our technology and practices. We use stem cells derived from human embryos that have been created for in vitro fertilization procedures but are no longer desired or suitable for that use and are donated with appropriate informed consent for research use. Many research institutions, including some of our scientific collaborators, have adopted policies regarding the ethical use of human embryonic tissue. These policies may have the effect of limiting the scope of research conducted using human embryonic stem cells, thereby impairing our ability to conduct research in this field.

*Despite the rescission of President Bush's Executive order in August 2001 by President Barack Obama in March 2009, the overall effect of new laws drafted by the NIH and put into effect regarding the dropping of restrictions on hES research has yet to be seen or made clear.*

While it is unclear whether Federal law continues to restrict the use of federal funds for human embryonic cell research, commonly referred to as hES cell research, there can be no assurance that our operations will not be restricted by any future legislative or administrative efforts by politicians or groups opposed to the development of hES cell technology or nuclear transfer technology. Additionally the executive order does not overturn the Dickey-Wicker Amendment, a 13-year-old ban on federal funding for the actual creation of new stem cell lines, an act that destroys an embryo. In the United States these efforts still must be funded privately or by state governments. Further, there can be no assurance that legislative or administrative restrictions directly or indirectly delaying, limiting or preventing the use of hES technology, nuclear transfer technology, IPS technology, the use of human embryonic material, or the sale, manufacture or use of products or services derived from nuclear transfer technology or other hES technology will not be adopted or extended in the future.

*Because we or our collaborators must obtain regulatory approval to market our products in the United States and other countries, we cannot predict whether or when we will be permitted to commercialize our products.*

Federal, state and local governments in the United States and governments in other countries have significant regulations in place that govern many of our activities. We are or may become subject to various federal, state and local laws, regulations and recommendations relating to safe working conditions, laboratory and manufacturing practices, the experimental use of animals and the use and disposal of hazardous or potentially hazardous substances used in connection with our research and development work. The preclinical testing and clinical trials of the products that we or our collaborators develop are subject to extensive government regulation that may prevent us from creating commercially viable products from our discoveries. In addition, the sale by us or our collaborators of any commercially viable product will be subject to government regulation from several standpoints, including manufacturing, advertising and promoting, selling and marketing, labeling, and distributing.

If, and to the extent that, we are unable to comply with these regulations, our ability to earn revenues will be materially and negatively impacted. The regulatory process, particularly in the biotechnology field, is uncertain, can take many years and requires the expenditure of substantial resources. Biological drugs and non-biological drugs are rigorously regulated. In particular, proposed human pharmaceutical therapeutic product candidates are subject to rigorous preclinical and clinical testing and other requirements by the FDA in the United States and similar health authorities in other countries in order to demonstrate safety and efficacy. We may never obtain regulatory approval to market our proposed products.

*Our products may not receive FDA approval, which would prevent us from commercially marketing our products and producing revenues.*

The FDA and comparable government agencies in foreign countries impose substantial regulations on the manufacture and marketing of pharmaceutical products through lengthy and detailed laboratory, pre-clinical and clinical testing procedures, sampling activities and other costly and time-consuming procedures. Satisfaction of these regulations typically takes several years or more and varies substantially based upon the type, complexity and novelty of the proposed product. We cannot assure you that FDA approvals for any products developed by us will be granted on a timely basis, if at all. Any such delay in obtaining, or failure to obtain, such approvals could have a material adverse effect on the marketing of our products and our ability to generate product revenue.

*For-profit entities may be prohibited from benefiting from grant funding.*

There has been much publicity about grant resources for stem cell research, including Proposition 71 in California. While the California Institute CIRM has provided grant funds to some for-profit entities, there is no guarantee that it will continue to do so, particularly given the state's current budgetary conditions. As a result of these uncertainties regarding Proposition 71, we cannot assure you that funding, if any, will be available to us.

*The government maintains certain rights in technology that we develop using government grant money and we may lose the revenues from such technology if we do not commercialize and utilize the technology pursuant to established government guidelines.*

Certain of our and our licensors' research has been or is being funded in part by government grants. In connection with certain grants, the U.S. government retains rights in the technology developed with the grant. These rights could restrict our ability to fully capitalize upon the value of this research.

## **Risks Related to International Regulation**

*We may not be able to obtain required approvals in other countries.*

The requirements governing the conduct of clinical trials and cell culturing and marketing of our product candidates outside the United States vary widely from country to country. Foreign approvals may take longer to obtain than FDA approvals and can require, among other things, additional testing and different clinical trial designs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval processes. Some foreign regulatory agencies also must approve prices of the products. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may negatively impact the regulatory process in others. We may not be able to file for regulatory approvals and may not receive necessary approvals to market our product candidates in any foreign country. If we fail to comply with these regulatory requirements or fail to obtain and maintain required approvals in any foreign country, we will not be able to sell our product candidates in that country and our ability to generate revenue will be adversely affected.

## **Financial Risks**

*We may not be able to raise the required capital to conduct our operations and develop and commercialize our products.*

We require substantial additional capital resources in order to conduct our operations and develop and commercialize our products and run our facilities. We will need significant additional funds or a collaborative partner, or both, to finance the research and development activities of our therapies and potential products. Accordingly, we are continuing to pursue additional sources of financing. Our future capital requirements will depend upon many factors, including:

- The continued progress and cost of our research and development programs,
- The progress with pre-clinical studies and clinical trials,
- The time and costs involved in obtaining regulatory clearance,
- The costs in preparing, filing, prosecuting, maintaining and enforcing patent claims,
- The costs of developing sales, marketing and distribution channels and our ability to sell the therapies/products if developed,
- The costs involved in establishing manufacturing capabilities for commercial quantities of our proposed products
- Competing technological and market developments,
- Market acceptance of our proposed products,
- The costs for recruiting and retaining employees and consultants, and
- The costs for educating and training physicians about our proposed therapies/products.

Additional financing through strategic collaborations, public or private equity financings or other financing sources may not be available on acceptable terms, or at all. Additional equity financing could result in significant dilution to our shareholders. Further, if additional funds are obtained through arrangements with collaborative partners, these arrangements may require us to relinquish rights to some of our technologies, product candidates or products that we would otherwise seek to develop and commercialize on our own. If sufficient capital is not available, we may be required to delay, reduce the scope of or eliminate one or more of our programs or potential products, any of which could have a material adverse affect on our financial condition or business prospects.

#### Risks Relating to Our Debt Financings

*There are a large number of shares underlying our debt in full, and warrants. The sale of these shares may depress the market price of our common stock.*

As of December 31, 2010, on an aggregated basis our debt and preferred stock financings may result in being converted into 6,400,425 shares of our common stock, and warrants and options that may be converted into approximately 183,307,361 shares of our common stock.

Sales of a substantial number of shares of our common stock in the public market could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate.

*The issuance of shares upon conversion of the convertible debentures and exercise of outstanding warrants will cause immediate and substantial dilution to our existing stockholders.*

The issuance of shares upon conversion of the convertible debentures and exercise of warrants, including the replacement warrants, will result in substantial dilution to the interests of other stockholders since the selling security holders may ultimately convert and sell the full amount issuable on conversion. Although no single selling security holder may convert its convertible debentures and/or exercise its warrants if such conversion or exercise would cause it to own more than 4.99% of our outstanding common stock, this restriction does not prevent each selling security holder from converting and/or exercising some of its holdings and then converting the rest of its holdings. In this way, each selling security holder could sell more than this limit while never holding more than this limit. There is no upper limit on the number of shares that may be issued which will have the effect of further diluting the proportionate equity interest and voting power of holders of our common stock.

*Our outstanding indebtedness on our Debentures imposes certain restrictions on how we conduct our business. In addition, all of our assets, including our intellectual property, are pledged to secure this indebtedness. If we fail to meet our obligations under the Debentures, our payment obligations may be accelerated and the collateral securing the debt may be sold to satisfy these obligations.*

The Debentures and related agreements contain various provisions that restrict our operating flexibility. Pursuant to the agreement, we may not, among other things:

- Except for certain permitted indebtedness, enter into, create, incur, assume, guarantee or suffer to exist any indebtedness for borrowed money of any kind, including but not limited to, a guarantee, on or with respect to any of its property or assets now owned or hereafter acquired or any interest therein or any income or profits therefrom,
- Except for certain permitted liens, enter into, create, incur, assume or suffer to exist any liens of any kind, on or with respect to any of its property or assets now owned or hereafter acquired or any interest therein or any income or profits therefrom,
- Amend our certificate of incorporation, bylaws or other charter documents so as to materially and adversely affect any rights of holders of the Debentures and Warrants,
- Repay, repurchase or offer to repay, repurchase or otherwise acquire more than a de minimis number of shares of our common stock or common stock equivalents,
- Enter into any transaction with any of our affiliates, which would be required to be disclosed in any public filing with the Securities and Exchange Commission, unless such transaction is made on an arm's-length basis and expressly approved by a majority of our disinterested directors (even if less than a quorum otherwise required for board approval),
- Pay cash dividends or distributions on any of our equity securities,

- Grant certain registration rights
- Enter into any agreement with respect to any of the foregoing, or
- Make cash expenditures in excess of \$1,000,000 per calendar month, subject to certain specified exceptions.

These provisions could have important consequences for us, including (i) making it more difficult for us to obtain additional debt financing from another lender, or obtain new debt financing on terms favorable to us, (ii) causing us to use a portion of our available cash for debt repayment and service rather than other perceived needs and/or (iii) impacting our ability to take advantage of significant, perceived business opportunities.

*Our obligations under our securities purchase agreements are secured by substantially all of our assets.*

Our obligations under certain security agreements, executed in connection with certain financings, with the holders of the debentures and warrants are secured by substantially all of our assets. As a result, if we default under the terms of the security agreement, such holders could foreclose on their security interest and liquidate all of our assets. This would cause operations to cease.

#### **Risks Related to Third Party Reliance**

*We depend on third parties to assist us in the conduct of our preclinical studies and clinical trials, and any failure of those parties to fulfill their obligations could result in costs and delays and prevent us from obtaining regulatory approval or successfully commercializing our product candidates on a timely basis, if at all.*

We engage consultants and contract research organizations to help design, and to assist us in conducting, our preclinical studies and clinical trials and to collect and analyze data from those studies and trials. The consultants and contract research organizations we engage interact with clinical investigators to enroll patients in our clinical trials. As a result, we depend on these consultants and contract research organizations to perform the studies and trials in accordance with the investigational plan and protocol for each product candidate and in compliance with regulations and standards, commonly referred to as "good clinical practice", for conducting, recording and reporting results of clinical trials to assure that the data and results are credible and accurate and the trial participants are adequately protected, as required by the FDA and foreign regulatory agencies. We may face delays in our regulatory approval process if these parties do not perform their obligations in a timely or competent fashion or if we are forced to change service providers.

*We depend on our collaborators to help us develop and test our proposed products, and our ability to develop and commercialize products may be impaired or delayed if collaborations are unsuccessful.*

Our strategy for the development, clinical testing and commercialization of our proposed products requires that we enter into collaborations with corporate partners, licensors, licensees and others. We are dependent upon the subsequent success of these other parties in performing their respective responsibilities and the continued cooperation of our partners. Under agreements with collaborators, we may rely significantly on such collaborators to, among other things:



- Design and conduct advanced clinical trials in the event that we reach clinical trials;
- Fund research and development activities with us;
- Pay us fees upon the achievement of milestones; and
- Market with us any commercial products that result from our collaborations.

Our collaborators may not cooperate with us or perform their obligations under our agreements with them. We cannot control the amount and timing of our collaborators' resources that will be devoted to our research and development activities related to our collaborative agreements with them. Our collaborators may choose to pursue existing or alternative technologies in preference to those being developed in collaboration with us.

*The development and commercialization of potential products will be delayed if collaborators fail to conduct these activities in a timely manner, or at all. In addition, our collaborators could terminate their agreements with us and we may not receive any development or milestone payments.*

If we do not achieve milestones set forth in the agreements, or if our collaborators breach or terminate their collaborative agreements with us, our business may be materially harmed.

*We are in a Strategic Joint Venture which may slow, impede or result in the termination of potential therapeutic products whose development is now the responsibility of the partnership and not solely of the Company.*

In 2008, the Company entered into a new partnership (CHA) and as a result, we are subject to 3rd party interests and control issues, not the least of which relates to certain of our employees no longer being exclusively managed by us. We therefore could be at risk for losing key employees. Additionally substantial operating and working capital will be required and there is no assurance that CHA Biotech Co. limited, partner in our joint venture, will be able to fund their requirements. Any failure on their part could negatively impact our product development, human capital and financial resources allocated to other of our programs.

*Our reliance on the activities of our non-employee consultants, research institutions, and scientific contractors, whose activities are not wholly within our control, may lead to delays in development of our proposed products.*

We rely extensively upon and have relationships with scientific consultants at academic and other institutions, some of whom conduct research at our request, and other consultants with expertise in clinical development strategy or other matters. These consultants are not our employees and may have commitments to, or consulting or advisory contracts with, other entities that may limit their availability to us. We have limited control over the activities of these consultants and, except as otherwise required by our collaboration and consulting agreements to the extent they exist, can expect only limited amounts of their time to be dedicated to our activities. These research facilities may have commitments to other commercial and non-commercial entities. We have limited control over the operations of these laboratories and can expect only limited amounts of time to be dedicated to our research goals.

#### **Preclinical & Clinical Product Development Risks**

*We have limited experience in conducting and managing preclinical development activities, clinical trials and the application process necessary to obtain regulatory approvals.*

Our limited experience in conducting and managing preclinical development activities, clinical trials and the application process necessary to obtain regulatory approvals might prevent us from successfully designing or implementing a preclinical study or clinical trial. If we do not succeed in conducting and managing our preclinical development activities or clinical trials, or in obtaining regulatory approvals, we might not be able to commercialize our product candidates, or might be significantly delayed in doing so, which will materially harm our business.

Our ability to generate revenues from any of our product candidates will depend on a number of factors, including our ability to successfully complete clinical trials, obtain necessary regulatory approvals and implement our commercialization strategy. In addition, even if we are successful in obtaining necessary regulatory approvals and bringing one or more product candidates to market, we will be subject to the risk that the marketplace will not accept those products. We may, and anticipate that we will need to, transition from a company with a research and development focus to a company capable of supporting commercial activities and we may not succeed in such a transition.

*Because of the numerous risks and uncertainties associated with our product development and commercialization efforts, we are unable to predict the extent of our future losses or when or if we will become profitable.*

Our failure to successfully commercialize our product candidates or to become and remain profitable could depress the market price of our common stock and impair our ability to raise capital, expand our business, diversify our product offerings and continue our operations.

*None of the products that we are currently developing has been approved by the FDA or any similar regulatory authority in any foreign country. Our approach of using cell-based therapy for the treatment of Retinal disease (we are beginning with a treatment for Startgardt's disease, for which we filed an IND with the FDA) is risky and unproven and no products using this approach have received regulatory approval in the United States or Europe.*

We believe that no company has yet been successful in its efforts to obtain regulatory approval in the United States or Europe of a cell-based therapy product for the treatment of retinal disease or degeneration in humans. Cell-based therapy products, in general, may be susceptible to various risks, including undesirable and unintended side effects, unintended immune system responses, inadequate therapeutic efficacy or other characteristics that may prevent or limit their approval by regulators or commercial use. Many companies in the industry have suffered significant setbacks in advanced clinical trials, despite promising results in earlier trials. If our clinical trials are unsuccessful or significantly delayed, or if we do not complete our clinical trials, we will not receive regulatory approval for or be able to commercialize our product candidates.

*Our lead product candidate, our therapeutic Retinal program for Startgardt's disease has not yet started Phase I Clinical Trials and has not yet received approval from the FDA or any similar foreign regulatory authority for any indication.*

We cannot market any product candidate until regulatory agencies grant approval or licensure. In order to obtain regulatory approval for the sale of any product candidate, we must, among other requirements, provide the FDA and similar foreign regulatory authorities with preclinical and clinical data that demonstrate to the satisfaction of regulatory authorities that our product candidates are safe and effective for each indication under the applicable standards relating to such product candidate. The preclinical studies and clinical trials of any product candidates must comply with the regulations of the FDA and other governmental authorities in the United States and similar agencies in other countries. Our therapeutic Retinal program may never receive approval from the FDA or any similar foreign regulatory authority.

*We may experience numerous unforeseen events during, or as a result of, the clinical trial process that could delay or prevent regulatory approval and/or commercialization of our product candidates, including the following:*

- The FDA or similar foreign regulatory authorities may find that our product candidates are not sufficiently safe or effective or may find our cell culturing processes or facilities unsatisfactory,
- Officials at the FDA or similar foreign regulatory authorities may interpret data from preclinical studies and clinical trials differently than we do,
- Our clinical trials may produce negative or inconclusive results or may not meet the level of statistical significance required by the FDA or other regulatory authorities, and we may decide, or regulators may require us, to conduct additional preclinical studies and/or clinical trials or to abandon one or more of our development programs,



- The FDA or similar foreign regulatory authorities may change their approval policies or adopt new regulations,
- There may be delays or failure in obtaining approval of our clinical trial protocols from the FDA or other regulatory authorities or obtaining institutional review board approvals or government approvals to conduct clinical trials at prospective sites,
- We, or regulators, may suspend or terminate our clinical trials because the participating patients are being exposed to unacceptable health risks or undesirable side effects,
- We may experience difficulties in managing multiple clinical sites,
- Enrollment in our clinical trials for our product candidates may occur more slowly than we anticipate, or we may experience high drop-out rates of subjects in our clinical trials, resulting in significant delays,
- We may be unable to manufacture or obtain from third party manufacturers sufficient quantities of our product candidates for use in clinical trials, and
- Our product candidates may be deemed unsafe or ineffective, or may be perceived as being unsafe or ineffective, by healthcare providers for a particular indication.

Any delay of regulatory approval will harm our business.

#### **Risks Related to Competition**

*The market for therapeutic stem cell products is highly competitive.*

We expect that our most significant competitors will be fully integrated pharmaceutical companies and more established biotechnology companies. These companies are developing stem cell-based products and they have significantly greater capital resources in research and development, manufacturing, testing, obtaining regulatory approvals, and marketing capabilities. Many of these potential competitors are further along in the process of product development and also operate large, company-funded research and development programs. As a result, our competitors may develop more competitive or affordable products, or achieve earlier patent recognition and filings.

*The biotechnology industries are characterized by rapidly evolving technology and intense competition. Our competitors include major multinational pharmaceutical companies, specialty biotechnology companies and chemical and medical products companies operating in the fields of regenerative medicine, cell therapy, tissue engineering and tissue regeneration.*

Many of these companies are well-established and possess technical, research and development, financial and sales and marketing resources significantly greater than ours. In addition, certain smaller biotech companies have formed strategic collaborations, partnerships and other types of joint ventures with larger, well established industry competitors that afford these companies' potential research and development and commercialization advantages. Academic institutions, governmental agencies and other public and private research organizations are also conducting and financing research activities which may produce products directly competitive to those we are developing. Moreover, many of these competitors may be able to obtain patent protection, obtain FDA and other regulatory approvals and begin commercial sales of their products before we do.

*In the general area of cell-based therapies (including both ES cell and autologous cell therapies), we compete with a variety of companies, most of whom are specialty biotechnology companies, such as Geron Corporation, Genzyme Corporation, StemCells, Inc., Aastrom Biosciences, Inc., Viacell, Inc., MG Biotherapeutics, Celgene, BioHeart, Inc., Baxter Healthcare, Osiris Therapeutics and Cytori.*

Each of these companies are well-established and have substantial technical and financial resources compared to us. However, as cell-based products are only just emerging as medical therapies, many of our direct competitors are smaller biotechnology and specialty medical products companies. These smaller companies may become significant competitors through rapid evolution of new technologies. Any of these companies could substantially strengthen their competitive position through strategic alliances or collaborative arrangements with large pharmaceutical or biotechnology companies.

*The diseases and medical conditions we are targeting have no effective long-term therapies. Nevertheless, we expect that our technologies and products will compete with a variety of therapeutic products and procedures offered by major pharmaceutical companies (in the Retinal Disease indication one of our primary competitors is Celgene). Many pharmaceutical and biotechnology companies are investigating new drugs and therapeutic approaches for the same purposes, which may achieve new efficacy profiles, extend the therapeutic window for such products, alter the prognosis of these diseases, or prevent their onset.*

We believe that our products, when and if successfully developed, will compete with these products principally on the basis of improved and extended efficacy and safety and their overall economic benefit to the health care system.

Competition for any stem cell products that we may develop may be in the form of existing and new drugs, other forms of cell transplantation, ablative and simulative procedures, and gene therapy. We believe that some of our competitors are also trying to develop stem and progenitor cell-based technologies. We expect that all of these products will compete with our potential stem cell products based on efficacy, safety, cost and intellectual property positions. We may also face competition from companies that have filed patent applications relating to the use of genetically modified cells to treat disease, disorder or injury. In the event our therapies should require the use of such genetically modified cells, we may be required to seek licenses from these competitors in order to commercialize certain of our proposed products, and such licenses may not be granted.

If we develop products that receive regulatory approval, they would then have to compete for market acceptance and market share. For certain of our potential products, an important success factor will be the timing of market introduction of competitive products. This timing will be a function of the relative speed with which we and our competitors can develop products, complete the clinical testing and approval processes, and supply commercial quantities of a product to market. These competitive products may also impact the timing of clinical testing and approval processes by limiting the number of clinical investigators and patients available to test our potential products.

*Our competition includes both public and private organizations and collaborations among academic institutions and large pharmaceutical companies, most of which have significantly greater experience and financial resources than we do.*

Private and public academic and research institutions also compete with us in the research and development of therapeutic products based on human embryonic and adult stem cell technologies. In the past several years, the pharmaceutical industry has selectively entered into collaborations with both public and private organizations to explore the possibilities that stem cell therapies may present for substantive breakthroughs in the fight against disease.

*The biotechnology and pharmaceutical industries are characterized by intense competition. We compete against numerous companies, both domestic and foreign, many of which have substantially greater experience and financial and other resources than we have. Several such enterprises have initiated cell therapy research programs and/or efforts to treat the same diseases targeted by us.*

Companies such as Geron Corporation, Genzyme Corporation, StemCells, Inc., Aastrom Biosciences, Inc. and Viacell, Inc., as well as others, many of which have substantially greater resources and experience in our fields than we do, are well situated to effectively compete with us. Any of the world's largest pharmaceutical companies represents a significant actual or potential competitor with vastly greater resources than ours. These companies hold licenses to genetic selection technologies and other technologies that are competitive with our technologies. These and other competitive enterprises have devoted, and will continue to devote, substantial resources to the development of technologies and products in competition with us.

*Many of our competitors have significantly greater experience than we have in the development, pre-clinical testing and human clinical trials of biotechnology and pharmaceutical products, in obtaining FDA and other regulatory approvals of such products and in manufacturing and marketing such products.*

Accordingly our competitors may succeed in obtaining FDA approval for products more rapidly or effectively than we can. Our competitors may also be the first to discover and obtain a valid patent to a particular stem cell technology which may effectively block all others from doing so. It will be important for us or our collaborators to be the first to discover any stem cell technology that we are seeking to discover. Failure to be the first could prevent us from commercializing all of our research and development affected by that discovery. Additionally, if we commence commercial sales of any products, we will also be competing with respect to manufacturing efficiency and sales and marketing capabilities, areas in which we have no experience.

#### **General Risks Relating to Our Business**

*We are subject to litigation that will be costly to defend or pursue and uncertain in its outcome.*

Our business may bring us into conflict with our licensees, licensors, or others with whom we have contractual or other business relationships, or with our competitors or others whose interests differ from ours. If we are unable to resolve those conflicts on terms that are satisfactory to all parties, we may become involved in litigation brought by or against us. That litigation is likely to be expensive and may require a significant amount of management's time and attention, at the expense of other aspects of our business. The outcome of litigation is always uncertain, and in some cases could include judgments against us that require us to pay damages, enjoin us from certain activities, or otherwise affect our legal or contractual rights, which could have a significant adverse effect on our business. See "LEGAL PROCEEDINGS" in this prospectus for a more complete discussion of currently pending litigation against the Company.

*We may not be able to obtain third-party patient reimbursement or favorable product pricing, which would reduce our ability to operate profitably.*

Our ability to successfully commercialize certain of our proposed products in the human therapeutic field may depend to a significant degree on patient reimbursement of the costs of such products and related treatments at acceptable levels from government authorities, private health insurers and other organizations, such as health maintenance organizations. We cannot assure you that reimbursement in the United States or foreign countries will be available for any products we may develop or, if available, will not be decreased in the future, or that reimbursement amounts will not reduce the demand for, or the price of, our products with a consequent harm to our business. We cannot predict what additional regulation or legislation relating to the health care industry or third-party coverage and reimbursement may be enacted in the future or what effect such regulation or legislation may have on our business. If additional regulations are overly onerous or expensive, or if health care related legislation makes our business more expensive or burdensome than originally anticipated, we may be forced to significantly downsize our business plans or completely abandon our business model.

*Our products are likely to be expensive to manufacture, and they may not be profitable if we are unable to control the costs to manufacture them.*

Our products are likely to be significantly more expensive to manufacture than most other drugs currently on the market today. Our present manufacturing processes produce modest quantities of product intended for use in our ongoing research activities, and we have not developed processes, procedures and capability to produce commercial volumes of product. We hope to substantially reduce manufacturing costs through process improvements, development of new science, increases in manufacturing scale and outsourcing to experienced manufacturers. If we are not able to make these or other improvements, and depending on the pricing of the product, our profit margins may be significantly less than that of most drugs on the market today. In addition, we may not be able to charge a high enough price for any cell therapy product we develop, even if they are safe and effective, to make a profit. If we are unable to realize significant profits from our potential product candidates, our business would be materially harmed.

*Our current source of revenues depends on the stability and performance of our sub-licensees.*

Our ability to collect royalties on product sales from our sub-licensees will depend on the financial and operational success of the companies operating under a sublicense. Revenues from those licensees will depend upon the financial and operational success of those third parties. We cannot assure you that these licensees will be successful in obtaining requisite financing or in developing and successfully marketing their products. These licensees may experience unanticipated obstacles including regulatory hurdles, and scientific or technical challenges, which could have the effect of reducing their ability to generate revenues and pay us royalties.

*We depend on key personnel for our continued operations and future success, and a loss of certain key personnel could significantly hinder our ability to move forward with our business plan.*

Because of the specialized nature of our business, we are highly dependent on our ability to identify, hire, train and retain highly qualified scientific and technical personnel for the research and development activities we conduct or sponsor. The loss of one or more certain key executive officers, or scientific officers, would be significantly detrimental to us. In addition, recruiting and retaining qualified scientific personnel to perform research and development work is critical to our success. Our anticipated growth and expansion into areas and activities requiring additional expertise, such as clinical testing, regulatory compliance, manufacturing and marketing, will require the addition of new management personnel and the development of additional expertise by existing management personnel. There is intense competition for qualified personnel in the areas of our present and planned activities, and there can be no assurance that we will be able to continue to attract and retain the qualified personnel necessary for the development of our business. The failure to attract and retain such personnel or to develop such expertise would adversely affect our business.

*Our credibility as a business operating in the field of human embryonic stem cells is largely dependent upon the support of our Ethics Advisory Board.*

Because the use of human embryonic stem cells gives rise to ethical, legal and social issues, we have instituted an Ethics Advisory Board. Our Ethics Advisory Board is made up of highly qualified individuals with expertise in the field of human embryonic stem cells. We cannot assure you that these members will continue to serve on our Ethics Advisory Board, and the loss of any such member may affect the credibility and effectiveness of the Board. As a result, our business may be materially harmed in the event of any such loss.

*Our insurance policies may be inadequate and potentially expose us to unrecoverable risks.*

We have limited director and officer insurance and commercial insurance policies. Any significant insurance claims would have a material adverse effect on our business, financial condition and results of operations. Insurance availability, coverage terms and pricing continue to vary with market conditions. We endeavor to obtain appropriate insurance coverage for insurable risks that we identify, however, we may fail to correctly anticipate or quantify insurable risks, we may not be able to obtain appropriate insurance coverage, and insurers may not respond as we intend to cover insurable events that may occur. We have observed rapidly changing conditions in the insurance markets relating to nearly all areas of traditional corporate insurance. Such conditions have resulted in higher premium costs, higher policy deductibles, and lower coverage limits. For some risks, we may not have or maintain insurance coverage because of cost or availability.

*We have no product liability insurance, which may leave us vulnerable to future claims we will be unable to satisfy.*

The testing, manufacturing, marketing and sale of human therapeutic products entail an inherent risk of product liability claims, and we cannot assure you that substantial product liability claims will not be asserted against us. We have no product liability insurance. In the event we are forced to expend significant funds on defending product liability actions, and in the event those funds come from operating capital, we will be required to reduce our business activities, which could lead to significant losses. We cannot assure you that adequate insurance coverage will be available in the future on acceptable terms, if at all, or that, if available, we will be able to maintain any such insurance at sufficient levels of coverage or that any such insurance will provide adequate protection against potential liabilities. Whether or not a product liability insurance policy is obtained or maintained in the future, any product liability claim could harm our business or financial condition.

*We presently have members of management and other key employees located in various locations throughout the country which adds complexities to the operation of the business.*

Presently, we have members of management and other key employees located in both California and Massachusetts, which adds complexities to the operation of our business.

*We face risks related to compliance with corporate governance laws and financial reporting standards.*

The Sarbanes-Oxley Act of 2002, as well as related new rules and regulations implemented by the Securities and Exchange Commission and the Public Company Accounting Oversight Board, require changes in the corporate governance practices and financial reporting standards for public companies. These new laws, rules and regulations, including compliance with Section 404 of the Sarbanes-Oxley Act of 2002 relating to internal control over financial reporting, referred to as Section 404, have materially increased our legal and financial compliance costs and made some activities more time-consuming and more burdensome.

#### **Risks Relating to Our Common Stock**

*Stock prices for biotechnology companies have historically tended to be very volatile.*

Stock prices and trading volumes for many biotechnology companies fluctuate widely for a number of reasons, including but not limited to the following factors, some of which may be unrelated to their businesses or results of operations:

- Clinical trial results,
- The amount of cash resources and ability to obtain additional funding,
- Announcements of research activities, business developments, technological innovations or new products by companies or their competitors,
- Entering into or terminating strategic relationships,
- Changes in government regulation,
- Disputes concerning patents or proprietary rights,
- Changes in revenues or expense levels,
- Public concern regarding the safety, efficacy or other aspects of the products or methodologies being developed,
- Reports by securities analysts,
- Activities of various interest groups or organizations,
- Media coverage, and
- Status of the investment markets.

This market volatility, as well as general domestic or international economic, market and political conditions, could materially and adversely affect the market price of our common stock and the return on your investment.

***A significant number of shares of our common stock have become available for sale and their sale could depress the price of our common stock.***

In 2008, a significant number of our outstanding securities that were previously restricted became eligible for sale under Rule 144 of the Securities Act, and their sale will not be subject to any volume limitations.

We may also sell a substantial number of additional shares of our common stock in connection with a private placement or public offering of shares of our common stock (or other series or class of capital stock to be designated in the future). The terms of any such private placement would likely require us to register the resale of any shares of capital stock issued or issuable in the transaction. We have also issued common stock to certain parties, such as vendors and service providers, as payment for products and services. Under these arrangements, we may agree to register the shares for resale soon after their issuance. We may also continue to pay for certain goods and services with equity, which would dilute your interest in the company.

Sales of a substantial number of shares of our common stock under any of the circumstances described above could adversely affect the market price for our common stock and make it more difficult for you to sell shares of our common stock at times and prices that you feel are appropriate.

***We do not intend to pay cash dividends on our common stock in the foreseeable future.***

Any payment of cash dividends will depend upon our financial condition, results of operations, capital requirements and other factors and will be at the discretion of our board of directors. We do not anticipate paying cash dividends on our common stock in the foreseeable future. Furthermore, we may incur additional indebtedness that may severely restrict or prohibit the payment of dividends.

***Our common stock is subject to "penny stock" regulations and restrictions on initial and secondary broker-dealer sales.***

The Securities and Exchange Commission (SEC) has adopted regulations which generally define "penny stock" to be any listed, trading equity security that has a market price less than \$5.00 per share or an exercise price of less than \$5.00 per share, subject to certain exemptions. Penny stocks are subject to certain additional oversight and regulatory requirements. Brokers and dealers affecting transactions in our common stock in many circumstances must obtain the written consent of a customer prior to purchasing our common stock, must obtain information from the customer and must provide disclosures to the customer. These requirements may restrict the ability of broker-dealers to sell our common stock and may affect your ability to sell your shares of our common stock in the secondary market.

***As an issuer of "penny stock," the protection provided by the federal securities laws relating to forward looking statements does not apply to us.***

Although federal securities laws provide a safe harbor for forward-looking statements made by a public company that files reports under the federal securities laws, this safe harbor is not available to issuers of penny stocks. As a result, the Company will not have the benefit of this safe harbor protection in the event of any legal action based upon a claim that the material provided by the Company contained a material misstatement of fact or was misleading in any material respect because of the Company's failure to include any statements necessary to make the statements not misleading. Such an action could hurt our financial condition.



**Item 1B. Unresolved Staff Comments**

None.

**Item 2. Properties**

Our headquarters are located in Marlboro, Massachusetts, where we lease approximately 10,607 square foot of office and laboratory facilities. The monthly rent for this property is \$12,596. The lease term is from April 1, 2010 through June 30, 2015. We also lease approximately 700 square feet of corporate office space in Santa Monica, CA. The lease for our Santa Monica office terminates on February 28, 2012. The monthly rent for this space is \$2,170.

**Item 3. Legal Proceedings**

*Gary D. Aronson v. Advanced Cell Technology, Inc., Superior Court of California, County of Alameda, Case No. RG07348990. John S. Gorton v. Advanced Cell Technology, Inc, Superior Court of California, County of Alameda Case No. RG07350437.* On October 1, 2007 Gary D. Aronson brought suit against us with respect to a dispute over the interpretation of the anti-dilution provisions of our warrants issued to Mr. Aronson on or about September 14, 2005. John S. Gorton initiated a similar suit on October 10, 2007. The two cases have been consolidated. The plaintiffs allege that we breached warrants to purchase securities issued by us to these individuals by not timely issuing stock after the warrants were exercised, failing to issue additional shares of stock in accordance with the terms of the warrants and failing to provide proper notice of certain events allegedly triggering Plaintiffs' purported rights to additional shares. The Plaintiffs withdrew their case the day before the trial date. We sought attorney fees relating to us defending the case over the past 2.5 years. The court denied the motion and we have appealed.

*Bristol Investment Fund, Ltd. as Collateral Agent for the Holders of Certain Original Issue Discount Senior Convertible Debentures v. Alexandria Real Estate—79/96 Charlestown Navy Yard, LLC (Suffolk Superior Court).* The Company has been named as a third party defendant in this action, filed September 16, 2009, in which the plaintiff alleges that Alexandria Real Estate ("Alexandria") improperly charged a trustee holding approximately \$146,000 of funds in a Company account that Bristol claimed as collateral. Alexandria brought a third party complaint against the Company for indemnification. The case was dismissed as of December 31, 2010.

On February 9, 2011, we entered into a settlement agreement and mutual release with Transition Holdings Ltd. ("Transition"), in a dispute over the \$3,500,000 received in 2008 and 2009. The two parties disputed the nature of the consideration provided to the Company. We agreed to deliver Transition 7,413,000 shares of our common stock, issuable in consideration of all monies previously delivered to the Company by Transition in the aggregate amount of \$3,500,000. Upon issuance of the shares, all other agreements between the Company and Transition, including licenses, are deemed cancelled, null and void, and of no force or effect.

On February 11, 2011, we entered into a settlement agreement and mutual release with Gemini Master Fund, Ltd. ("Gemini"). The two parties disputed the number of shares of common stock to be issued upon exercise of warrants held by Gemini. In settlement, we agreed to deliver Gemini 20,000,000 shares of its common stock, issuable upon cashless exercise of all warrants previously issued by the Company to Gemini. Upon issuance of the shares to Gemini, all other agreements between the Company and Gemini, including any agreements between the Company and any entity controlled by Gemini or their principals, are hereby deemed cancelled, null and void, and of no force or effect.

**Item 4. [Reserved]**

Not applicable.

## PART II

### Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities

#### Market Information

Our common stock is quoted on the OTCBB under the symbol "ACTC.OB." For the periods indicated, the following table sets forth the high and low bid prices per share of our common stock. These prices represent inter-dealer quotations without retail markup, markdown, or commission and may not necessarily represent actual transactions.

	High Bid	Low Bid
Fiscal Year 2009		
First Quarter	\$ 0.29	\$ 0.04
Second Quarter	\$ 0.27	\$ 0.10
Third Quarter	\$ 0.24	\$ 0.12
Fourth Quarter	\$ 0.13	\$ 0.09

	High Bid	Low Bid
Fiscal Year 2010		
First Quarter	\$ 0.12	\$ 0.08
Second Quarter	\$ 0.10	\$ 0.07
Third Quarter	\$ 0.09	\$ 0.05
Fourth Quarter	\$ 0.27	\$ 0.04

Trades of our common stock are subject to Rule 15c-9 of the Securities and Exchange Commission, known as the Penny Stock Rule. This rule imposes requirements on broker/dealers who sell securities subject to the rule to persons other than established customers and accredited investors. For transactions covered by the rule, brokers/dealers must make a special suitability determination for purchasers of the securities and receive the purchaser's written agreement to the transaction prior to sale. The Securities and Exchange Commission also has rules that regulate broker/dealer practices in connection with transactions in "penny stocks." Penny stocks generally are equity securities with a price of less than \$5.00, other than securities registered on certain national securities exchanges or quoted on the NASDAQ system, provided that current price and volume information with respect to transactions in that security is provided by the exchange or system. The Penny Stock Rules requires a broker/dealer, prior to a transaction in a penny stock not otherwise exempt from the rules, to deliver a standardized risk disclosure document prepared by the Commission that provides information about penny stocks and the nature and level of risks in the penny stock market. The broker/dealer also must provide the customer with current bid and offer quotations for the penny stock, the compensation of the broker/dealer and its salesperson in the transaction, and monthly account statements showing the market value of each penny stock held in the customer's account. The bid and offer quotations, and the broker/dealer and salesperson compensation information, must be given to the customer orally or in writing prior to effecting the transaction and must be given to the customer in writing before or with the customer's confirmation. These disclosure requirements have the effect of reducing the level of trading activity in the secondary market for our common stock. As a result of these rules, investors may find it difficult to sell their shares.

#### Holders

As of March 11, 2011, there were approximately 235 shareholders of record of our common stock.

#### Dividends

We have never paid cash dividends and have no plans to do so in the foreseeable future. Our future dividend policy will be determined by our board of directors and will depend upon a number of factors, including our financial condition and performance, our cash needs and expansion plans, income tax consequences, and the restrictions that applicable laws, our current preferred stock instruments, and our future credit arrangements may then impose.



Currently under Delaware law, unless further restricted in its certificate of incorporation, a corporation may declare and pay dividends out of surplus, or if no surplus exists, out of net profits for the fiscal year in which the dividend is declared and/or the preceding fiscal year (provided that the amount of capital of the corporation is not less than the aggregate amount of the capital represented by the issued and outstanding stock of all classes having a preference upon the distribution of assets).

**Securities Authorized for Issuance Under Equity Compensation Plans**

The following table shows information with respect to each equity compensation plan under which the Company's common stock is authorized for issuance as of the fiscal year ended December 31, 2010.

**EQUITY COMPENSATION PLAN INFORMATION**

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted average exercise price of outstanding options, warrants and rights	Number of securities remaining available for issuance under equity compensation plans (excluding securities reflected in column (a))
	(a)	(b)	(c)
Equity compensation plans approved by security holders	48,376,119(1) \$	0.23	131,621,494(2)
Equity compensation plans not approved by security holders	3,201,943	0.56	-
<b>Total</b>	<b>51,578,062</b>	<b>0.25</b>	<b>131,621,494</b>

(1) Awards for 2,492,000 options have been issued under the Advanced Cell Technology, Inc. 2004 Stock Option Plan I ("2004 Plan I"), 1,301,161 options have been issued under the Advanced Cell Technology, Inc. 2004 Stock Option Plan II ("2004 Plan 2" and together with the 2004 Plan I, the "2004 ACT Plans"), and 49,495,484 options have been issued under the 2005 Stock Plan.

(2) This number included 370,000 shares available under the 2004 Plan I, 230,000 shares available under the 2004 Plan II and 131,021,494 shares available under the 2005 Stock Plan.

**Recent Sales of Unregistered Securities; Uses of Proceeds From Registered Securities**

***Recent Sales of Unregistered Securities***

During the year ended December 31, 2010, the Company issued 31,399,587 shares of its common stock in a cashless exercise of warrants. These shares were eligible for sale under the Rule 144.

On February 11, 2011, the Company issued 7,413,000 shares of its common stock to Transition Holdings, Ltd. pursuant to a settlement agreement and mutual release between the Company and the investor.